

RULEMAKING ISSUE AFFIRMATION

October 31, 2006

SECY-06-0220

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: FINAL RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS,
AND APPROVALS FOR NUCLEAR POWER PLANTS" (RIN AG24)

PURPOSE:

To obtain Commission approval to publish in the *Federal Register* final amendments to Title 10, Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," of the *Code of Federal Regulations* (10 CFR Part 52) which would also retitle 10 CFR Part 52 and make conforming changes to related sections of the regulations in Title 10, Chapter 1.

SUMMARY:

The Nuclear Regulatory Commission (NRC) staff (the staff) is seeking Commission approval of final amendments to its regulations at 10 CFR Part 52 concerning the licensing and approval processes for nuclear power plants. The final rule rewrites 10 CFR Part 52, modifies other NRC regulations to enhance the Agency's effectiveness and efficiency in implementing the 10 CFR Part 52 licensing and approval processes, and clarifies the applicability of various requirements to each of these processes (*i.e.*, early site permit (ESP), standard design approval, standard design certification, combined license (COL), and manufacturing license).

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The enhancements to 10 CFR Part 52 are the result of lessons learned during design certification and ESP reviews and stakeholder discussions about the ESP, design certification, and COL review processes.

On July 3, 2003 (68 FR 40026), the NRC published in the *Federal Register* a proposed rule to clarify regulations related to nuclear power plant licensing under 10 CFR Part 52. After further consideration, the NRC published a revised proposal of these rule amendments on March 13, 2006 (71 FR 12781). The public comment period for the March 2006 revised proposed rule closed on May 30, 2006. The NRC received 19 comment letters from industry stakeholders, other Federal agencies, and individuals during the public comment period. The NRC staff has considered and resolved all of the public comments received during the comment period and has modified the rule language, as appropriate. The staff has prepared a separate report, entitled *Comment Summary Report: 10 CFR Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants*, in which it summarizes the public comments received during the comment period and discusses the staff's disposition of each comment (Enclosure 3). The resolution of significant public comments is also discussed in Section IV, "Responses to Specific Requests for Comments" and, Section V, "Discussion of Substantive Changes and Responses to Significant Comments" of the enclosed *Federal Register* notice. The staff believes that this final rulemaking will improve the effectiveness and efficiency of the licensing and approval processes in 10 CFR Part 52 for future applicants. In SECY-06-0180, "Supplemental Proposed Rulemaking on Limited Work Authorizations," dated August 14, 2006, the staff and the Office of the General Counsel (OGC) separately transmitted a proposed supplement to the 10 CFR Part 52 rule amending the Commission's regulations concerning limited work authorizations (LWAs) under 10 CFR 50.10, "License Required." The Commission approved publication of the supplemental proposed rule on October 2, 2006, and the rule was published for comment in the *Federal Register* on October 17, 2006 (71 FR 61330). The public comment period for the supplemental proposed rule closes on November 16, 2006. The objective of the staff and OGC is that the Commission would approve the LWA changes in a manner such that the LWA provisions could be published in the *Federal Register* as part of the final Part 52 rule.

BACKGROUND:

The NRC staff planned to update 10 CFR Part 52 after the first standard design certification reviews. The proposed rulemaking action began with the issuance of SECY-98-282, "Part 52 Rulemaking Plan," on December 4, 1998 (Agencywide Documents Access and Management Systems (ADAMS) Accession No. ML032801416). The Commission issued a staff requirements memorandum (SRM) on January 14, 1999 (ADAMS Accession No. ML032801439), approving the staff's plan for revising 10 CFR Part 52. Subsequently, the NRC staff obtained considerable stakeholder comment on its planned action. On July 3, 2003, the NRC published a proposed rule to clarify miscellaneous parts of the NRC's regulations, update 10 CFR Part 52 in its entirety, and incorporate stakeholder comments.

Following the close of the public comment period on the July 2003 proposed rule, a number of factors led the staff to question whether this proposed rule would meet the Commission's objective of improving the effectiveness of NRC processes for licensing future nuclear power plants. Public comments identified several concerns about whether the proposed rule adequately addressed the relationship between 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52. Some commenters also questioned

whether the proposed rule clearly specified the applicable regulatory requirements for each of the licensing and approval processes in 10 CFR Part 52.

In addition, through its review of the first three ESP applications, the staff gained additional insights into the ESP process. The staff also benefitted from public meetings with external stakeholders on the development of staff guidance on the ESP and COL processes. As a result, the staff decided that, to more effectively and efficiently implement the licensing and approval processes for nuclear power plants in 10 CFR Part 52, a substantial rewrite and expansion of the original proposed rulemaking to include changes throughout the entire body of NRC regulations in Title 10, Chapter 1, was necessary. The staff again considered previously submitted comments in developing the most recent proposed rule. On August 25, 2005, the Agency posted draft rule language on the NRC rulemaking Web site and, on September 6, 2005 (70 FR 52942), published a notice of the availability of the draft rule language in the *Federal Register*. On March 13, 2006, the NRC published a revised proposed rule superseding the July 2003 proposed rule.

On March 14, 2006, the NRC staff convened a public workshop to facilitate discussion on the rulemaking and to answer stakeholder questions regarding the revised proposed rule. A summary of that workshop and the transcript are available on the NRC's Web site (ADAMS Accession Nos. ML060970324 and ML060810669, respectively). In response to stakeholder requests, the staff convened a public meeting on April 18, 2006, to discuss specific questions about the requirements of the revised proposed rule pertaining to LWAs and the severe accident design features necessary for design certification. A summary of that meeting is available on the NRC Web site (ADAMS Accession No. ML061140433).

DISCUSSION:

As discussed in the *Federal Register* notice (Enclosure 1) and in SECY-05-0203, "Revised Proposed Rule to Update 10 CFR Part 52, 'Licenses, Certifications, and Approvals for Nuclear Power Plants,'" dated November 3, 2005 (ADAMS Accession No. ML052300372), this rulemaking rewrites 10 CFR Part 52 to improve the organization, format, and language. The final rule also contains changes to other NRC regulations to clarify the applicability of various technical and regulatory requirements throughout Title 10, Chapter 1, to each of the processes in 10 CFR Part 52.

Rule changes necessary to implement the objectives of the Part 52 rulemaking have been conformed to refer to the Director of the Office of New Reactors. This should minimize the need for conforming reviews of the Part 52 rulemaking before final publication in the *Federal Register*. However, this does not eliminate the need for a general review of, and conforming administrative changes to, existing Title 10, Chapter 1, regulations.

The staff has redesignated former Appendices O and M of 10 CFR Part 52 on standard design approvals and manufacturing licenses, respectively, as new subparts in the revised 10 CFR Part 52. Redesignating these appendices as subparts results in a consistent format and organization of the requirements applicable to the main licensing and approval processes in 10 CFR Part 52. In addition, the redesignation clarifies that each of these licensing processes are available to potential applicants as an alternative to the licensing and approval processes in 10 CFR Part 50 (construction permit and operating license). Consistent with the broad scope of

10 CFR Part 52, the final rule is retitled, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The revised 10 CFR Part 52 contains five subparts—ESPs (Subpart A), design certifications (Subpart B), COLs (Subpart C), design approvals (Subpart E), and manufacturing licenses (Subpart F). The staff proposes to reserve Subpart D for possible future use.

The staff retained Appendices N and Q of 10 CFR Part 52 in the final rule, but had proposed to remove them in the proposed rule. Appendix N to 10 CFR Part 52, which addresses duplicate design licenses, is discussed later in this paper. The staff has also chosen to retain Appendix Q to 10 CFR Part 52, which addresses early staff review of site suitability issues. Appendix Q allows the NRC staff to issue a report on site suitability issues for a specific site for which a potential applicant seeks the NRC staff’s input. This process is separate from the ESP process discussed in Subpart A of 10 CFR Part 52. Although there is some redundancy between the early review of site suitability issues and the ESP process, to allow ESP and COL applicants maximum flexibility in seeking early review of issues, the staff has retained Appendix Q to 10 CFR Part 52 in the final rule. This change from the proposed rule is based largely on public comments.

The staff also reorganized and expanded the scope of the administrative and general regulatory provisions that precede the 10 CFR Part 52 subparts by adding new sections analogous to 10 CFR 50.4, “Written Communications,” 10 CFR 50.7, “Employee Protection,” 10 CFR 50.9, “Completeness and Accuracy of Information,” 10 CFR 50.12, “Exemptions,” 10 CFR 50.13, “Attacks and Destructive Acts,” 10 CFR 50.52, “Combining Licenses,” and 10 CFR 50.53, “Jurisdictional Limits.” Adding the new sections to 10 CFR Part 52 rather than revising the comparable sections in 10 CFR Part 50 is more consistent with the general format and content of the Commission’s regulations.

The staff reviewed the existing regulations in Title 10, Chapter 1, to determine whether they require modification to reflect the licensing and approval processes in 10 CFR Part 52. This review had two aspects. First, the staff determined whether an existing regulatory provision must, by virtue of a statutory requirement or regulatory necessity, be extended to address a 10 CFR Part 52 process and, if so, how the regulatory provision should apply. Second, in situations in which the Commission has some discretion, the staff determined whether there were policy or regulatory reasons to extend the existing regulations to each of the 10 CFR Part 52 processes. Most of the staff’s conforming changes occur in 10 CFR Part 50. In making changes involving the 10 CFR Part 50 provisions, the staff adopted the general principle of retaining the technical requirements in 10 CFR Part 50 and maintaining all applicable procedural requirements in 10 CFR Part 52. However, because of the complexity of some provisions in 10 CFR Part 50 (e.g., 10 CFR 50.34, “Contents of Applications; Technical Information”), the staff could not universally follow this principle. The enclosed *Federal Register* notice provides a description of, and bases for, the conforming changes for each affected part.

The staff has revised the regulatory analysis prepared for the proposed rule based on the changes made to the final rule. Enclosure 2 to this paper provides the revised regulatory analysis.

The following discussion highlights for Commission consideration several new staff proposals in the final rulemaking:

- ESP Finality on Environmental Issues
- Design Certification Amendments
- Completion of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) under a COL
- Changes to Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders”
- COLs of Identical Design at Multiple Sites

ESP Finality on Environmental Issues

The staff made several changes in the final rule based on public comments regarding the requirements for a COL application referencing an ESP and based on further consideration of the NRC’s obligations under the National Environmental Policy Act (NEPA) for such actions. In the proposed rule, 10 CFR Part 51 would have required the preparation of an environmental impact statement (EIS) for all COLs referencing an ESP. Several commenters believed that an ESP and COL met the Council on Environmental Quality (CEQ) regulation definition of “connected actions,” and should therefore not require the preparation of a new EIS for the second of the two connected actions, or a revalidation of previous findings if neither the applicant nor others identify new and significant information. Commenters stated that under NEPA case law, there was no requirement to prepare a new EIS for the latter of the two connected actions that were previously evaluated together in a single EIS. The commenters stated that the EIS prepared at the ESP stage serves as the EIS for issuance of both the ESP and COL. Commenters stated that the ESP EIS included an evaluation of the environmental impacts related to issuance of a COL inasmuch as it considered the environmental impact of plant construction and operation.

The staff continues to believe that it is not necessary to require that all topics be covered in a single EIS at the ESP stage, and that topics such as alternative energy sources and need for power may be treated in an EIS supplement at the COL stage when the detailed planning for the project is completed. As the commenters note, new and significant information may also prompt the preparation of a supplement to the ESP EIS in connection with the COL application. The staff has modified the final rule to limit the preparation of a supplementary EIS to those situations. In view of this resolution of the ESP finality issue, which addresses much of stakeholders’ concerns in this area, the staff and OGC believe that the final rule need not state a position on whether the granting of an ESP and the granting of a COL referencing that ESP are connected actions. Nonetheless, if detailed planning and associated environmental information is in fact complete when an ESP application is filed, there is no bar to the staff to prepare, at the ESP stage, an EIS that resolves all environmental matters associated with construction and operation of a power reactor at the ESP site, including the benefits of such construction and operation (e.g., need for power), and alternative energy sources. The staff may then rely on that EIS at the COL stage, provided that new and significant information has

not been identified. The staff need not label the ESP and COL as connected actions to adopt this procedure. Accordingly, the staff has modified the final rule to allow for an ESP EIS to serve as the EIS for a COL application referencing the ESP without supplementation under such circumstances. In those cases, the staff is proposing to issue an environmental assessment (EA) with a finding of no new and significant information. The final rule provides that the staff will prepare a draft EA with a proposed finding of no new and significant information for a COL application referencing an ESP only if: (1) the final environmental impact statement prepared in connection with the ESP discloses the economic, technical, or other benefits (e.g., need for power) and costs of the proposed action, contains an evaluation of alternative energy sources and resolves all environmental issues related to the impacts of construction and operation of the facility; and (2) there is no new and significant information identified with respect to issues related to the impacts of construction and operation of the facility that were resolved in the ESP proceeding. The draft EA and proposed finding would be issued for public comment. Following the close of the public comment period, the staff would prepare a recommended final EA and finding of no new and significant information to be issued by the Commission itself. Thus, the Commission itself would act as the presiding officer with respect to NEPA matters in this situation. OGC believes that these changes may meet the "logical outgrowth" test inasmuch as the Commission posed specific questions on how the NRC would address its NEPA obligations where a combined license application references an ESP. In addition, the Part 51 changes constitute changes to the NRC's rules of practice and procedure, inasmuch as Part 51 describes the manner in which the NRC will fulfill its NEPA obligations. NEPA is a procedural statute, and does not impose substantive obligations on a Federal agency. Therefore, the changes to Part 51 may be adopted in final form without further notice of opportunity for public comment.

Some members of the Office of Nuclear Reactor Regulation (NRR) staff believe that the change allowing preparation of an EA with a finding of no new and significant information for a COL application referencing an ESP is a significant departure from the approach in the 1989 rule. These staff members believe that the new approach warrants consideration by external stakeholders, such as other Federal agencies that have traditionally been interested in the EISs prepared in support of authorization of construction permits and operating licenses. Furthermore, these staff members believe that the approach proposed for the final rule represents a significant departure from the draft proposed rule and are concerned that external stakeholders have not had an opportunity to comment on the specifics of this alternative approach. In addition, the same staff members believe that an Agency position on the "connected actions" issue is a policy matter that the Commission should resolve to preclude ambiguity in light of the fact that some comments on the proposed rule reflected the view that issuance of an ESP and issuance of a COL referencing that ESP are connected actions. These staff members believe that an agency may take a major Federal action (such as issuing a COL) without preparing an EIS only if the action is connected to a previous agency action with a supporting EIS that covers the same purpose and need as the follow on action. The staff and OGC have considered these matters and continue to support the final rule as presented in Enclosure 1.

Another area of significant public comment was concern about the perceived loss of finality previously awarded to environmental issues addressed in an ESP. Commenters were concerned that, under the proposed rule, interveners could litigate a previously evaluated environmental issue simply by alleging that new information existed which altered the prior

conclusions. The staff agreed with the commenters that the rule language should be modified in the final rule to reflect more clearly the finality of environmental issues resolved in an ESP.

Therefore, the final rule limits environmental contentions that may be litigated to “any significant environmental issue related to the impacts of construction and operation of the facility that was not previously resolved in the proceeding on the ESP application, or any issue involving the impacts of construction and operation of the facility that was previously resolved in the proceeding on the ESP application for which new and significant information has been identified.” The staff believes that the regulations and the applicable case law interpreting NEPA allow the staff to incorporate the ESP EIS by reference in the COL EIS. However, the staff must address any new and significant information for issues that were resolved in the ESP EIS.

Another issue raised by commenters was the definition of “new and significant” information in the proposed rule as it applies in the context of a COL application referencing an ESP. Commenters were opposed to wording in the text of the proposed rule that would require COL applications to include, “any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit environmental impact statement.” Commenters stated that a COL applicant should only provide information about a previously considered environmental issue if it is both new and significant, not simply different from or in addition to previously presented information.

The staff agrees with the commenters and has modified 10 CFR Part 51 in the final rule to require that COL applicants referencing an ESP include any new and significant information for issues related to the impacts of construction and operation of the facility that were resolved in the ESP proceeding. Conversely, matters related strictly to siting (*i.e.*, evaluation of alternative sites and a determination of whether there is an obviously superior alternative site), are finally resolved at the ESP stage and there is no need to provide new and significant information on those matters. The staff, in the context of a combined license application that references an ESP, has defined the term “new” in the phrase “new and significant information” as any information that was both (1) not considered in preparing the ESP environmental report or EIS (as may be evidenced by references in these documents, applicant responses to NRC requests for additional information, comment letters, etc.) and (2) not generally known or publicly available during the preparation of the EIS (such as information in reports, studies, and treatises). This new information may or may not be significant. For an issue to be significant, it must be material to the issue being considered, *i.e.*, it must have the potential to affect the finding or conclusions of the NRC staff’s evaluation of the issue. The COL applicant need only provide information about a previously resolved environmental issue if it is both new and significant. The NRC staff will verify that the applicant’s process for identifying new and significant information is effective.

Design Certification Amendments

In Section V of the proposed rule (Question #14), the Commission stated that it was considering adopting an additional provision in 10 CFR 52.63(a)(1) that would allow amendments of design certification rules (DCRs) to incorporate generic resolutions of design acceptance criteria (DAC) or other design information without meeting the special backfit requirement in the former 10 CFR 52.63(a)(1). By allowing for a DCR amendment to generically resolve DAC, the

Commission would resolve additional design issues, would achieve finality for those issue resolutions, and would avoid repetitive consideration of those design issues in individual COL proceedings.

In response to Question #14, many commenters encouraged the NRC to include a process that would allow for amendments to the DCR to incorporate “beneficial” changes resulting from first-of-a-kind engineering, would apply the amendment to all plants referencing the certified design, and would only allow amendments before issuance of the first COL that referenced the DCR. Some commenters also proposed that the amendment process allow for generic resolutions of errors in the certification information or design changes that result from lack of availability of components specified in the original DCR.

The staff’s deliberations on these proposals considered the Commission’s goal for design certification, which is to achieve and maintain the benefits of standardization. The Commission stated in the original 10 CFR Part 52 (April 18, 1989; 54 FR 15372) that achievement of the enhanced safety, made possible by standardization will be frustrated if changes to either a certified design or the plants referencing it are permitted too frequently. As a result, the former 10 CFR 52.63(a)(1) contained a special backfit requirement to restrict changes and to require that everyone meet the same backfit standard for generic changes, thereby ensuring that all plants built under a referenced DCR would be standardized. The staff is still determined to achieve the benefits of standardization, but recommends allowing amendments of certification information provided the amendment will be applied to all plants that reference the DCR. In determining whether to codify a proposed amendment, the NRC will give special consideration to comments from applicants or licensees who reference the DCR regarding whether they want to backfit their plants with these additional design changes.

Therefore, the staff has included in the final rule a DCR amendment process in 10 CFR 52.63(a)(1) for Commission consideration. The process allows for: (1) generic resolutions of DAC; (2) correction of errors; or (3) increasing standardization, without meeting the special backfit requirement. These amendments will apply to all plants that have referenced or will reference the DCR. The staff believes that these amendments will enhance standardization by further completing or correcting the certification information. A detailed discussion of the comments on the amendment process is provided in Section V.C.7.g of the final rule.

Completion of ITAAC Under a COL

After consideration of the tasks that must be completed to support a Commission finding that the acceptance criteria in the COL are met (under 10 CFR 52.103(g)), the staff has made several changes to the regulations governing ITAAC. The staff has added a new § 52.99(a) in the final rule to require that a licensee submit to the NRC, no later than 1 year after issuance of the COL, its detailed schedule for completing the inspections, tests, or analyses in the ITAAC. This provision also requires the licensee to submit updates to the ITAAC schedule every 6 months thereafter. Within 1 year of its scheduled date for initial loading of fuel, the licensee must submit updates to the ITAAC schedule every 30 days. In the proposed rule, the NRC sought stakeholder feedback on whether the final rule should include such a provision. Although commenters did not believe that a regulatory requirement for submission of a schedule was necessary, the staff disagrees. An ITAAC schedule is necessary to ensure that the NRC has sufficient information to plan all of the activities required for the staff to support the

Commission's timely determination as to whether all of the ITAAC were met before the licensee's scheduled date for fuel load.

The staff has made further changes in the final rule to the proposed 10 CFR 52.99(c), which requires the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC were completed and the acceptance criteria met. The staff has modified 10 CFR 52.99(c) in the final rule to clarify, in paragraph (c)(1), that the notification must contain sufficient information to demonstrate that the acceptance criteria for the ITAAC were met. The staff is adding this clarification to ensure that COL applicants and holders are aware that the NRC expects the notification of ITAAC completion to contain more information than just a simple statement that the licensee believes the ITAAC were completed and the acceptance criteria met. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes "sufficient information" for such a demonstration. In addition, the staff has added a new paragraph (c)(2) requiring that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) for all ITAAC, then the licensee must notify the NRC that the inspections, tests, or analyses for all uncompleted ITAAC will be successfully completed and all acceptance criteria will be met prior to initial operation (consistent with the Atomic Energy Act (AEA), Section 185.b, requirement that the Commission, "prior to operation," find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the inspections, tests, or analyses will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met. Paragraph (e) has been revised to require that the NRC make available to the public the notifications to be submitted under § 52.99(c)(1) and (c)(2), no later than the *Federal Register* notice of intended operation and opportunity for hearing on ITAAC under § 52.103(a). A conforming change is included in § 2.105(b)(3) to require that the § 52.103(a) notice reference the public availability of the § 52.99(c)(1) and (2) notifications. The staff is proposing that the paragraph (c)(2) notification be set at 225 days before the date scheduled for initial loading of fuel, in order to ensure that the licensee notifications are publicly available through the NRC document room and online through the NRC Web site at the same time that the § 52.103(a) notice is published in the *Federal Register*. The staff's goal is to publish that notice 210 days before the date scheduled for fuel loading, but in all cases the § 52.103(a) notice would be published no later than 180 days before scheduled fuel load, as required by Section 189.a(1)(B) of the AEA.

In the proposed rule, the NRC requested stakeholder feedback on whether a provision on completion of ITAAC in a set time period prior to fuel load should be added to the final rule. Commenters did not support addition of such a requirement, and the staff has not included a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date. Instead, the staff has decided to modify the concept slightly by requiring the licensee to submit, with respect to ITAAC which have not yet been completed 225 days before the scheduled date for initial loading of fuel, additional information addressing whether those inspections, tests, and analyses will be successfully completed and the acceptance criteria met before initial operation. The staff believes it is necessary to add the new provision in § 52.99(c)(2) to ensure it has sufficient information to complete all of the

activities necessary for the Commission to make a determination as to whether all of the ITAAC have been or will be met prior initial operation. In the case where the licensee has not completed all ITAAC by 225 days prior to its scheduled fuel load date, the staff expects the information that the licensee submits related to uncompleted ITAAC to be sufficiently detailed such that it can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the staff that those ITAAC have been successfully completed and their acceptance criteria met. In addition, the staff is adding the requirements in paragraphs (c)(1) and (c)(2) to ensure that interested persons will be able to meet the AEA, Section 189.a(1), threshold for a hearing with respect to both completed and as-yet uncompleted ITAAC. The staff therefore expects that the information submitted by licensees in the § 52.99(c)(2) notification will be sufficiently complete and detailed such that any licensee response to a contention on either completed or uncompleted ITAAC would ordinarily be answered solely by reference to information contained in the notification. Furthermore, the staff expects that any contentions submitted by prospective interveners regarding uncompleted ITAAC would focus on the inadequacies of the procedures and analytical methods described by the licensee for completing those ITAAC in the context of the reasonable assurance finding under 10 CFR 52.103(b)(2). Therefore, the level of detail provided by the licensee should be sufficient to allow a prospective intervener to form such judgments by reference to that information. The staff plans to prepare regulatory guidance providing further explanation of what constitutes “sufficient information” to demonstrate that the inspections, tests, or analyses for uncompleted ITAAC will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met.

The staff notes that, even though it did not include a provision requiring the completion of all ITAAC by a certain time prior to the licensee’s scheduled fuel load date, the staff will require some period of time to perform its review of the last ITAAC once the licensee submits its notification that the ITAAC has been successfully completed and the acceptance criteria met. In addition, the Commission will require some period of time to perform its review of the staff’s conclusions regarding all of the ITAAC and the staff’s recommendations regarding the Commission finding under 10 CFR 52.103(g). The staff notes in the “Supplementary Information” section of the attached *Federal Register* notice that licensees should structure their construction schedules to take into account these time periods. The staff intends to develop regulatory guidance on the licensee’s completion and NRC verification of ITAAC and will provide estimates of the time it expects to take to verify successful completion of various types of ITAAC. The staff expects that such guidance, along with frequent communication with licensees during construction, will provide licensees with adequate information to plan initial fuel loading and related activities.

Changes to 10 CFR Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders”

In the March 2006 proposed rule, changes to 10 CFR Part 2 were largely limited to conforming changes to address Part 52 processes, including design certifications in Subpart H. However, in response to public comments, the staff is proposing additional changes to 10 CFR Part 2 regarding the NRC’s rules of practice and procedure. Such changes can be made in the final 10 CFR Part 52 rule without renoting under the Administrative Procedures Act (APA) (52 U.S.C. 553(b)(A)).

The staff revised 10 CFR 2.101(a-1) and Subpart F of 10 CFR Part 2 to provide for early consideration and a partial early decision on site suitability issues associated with an application for a COL. Currently, 10 CFR 2.101(a-1) and Subpart F may be used only in connection with applications for construction permits.

The staff is revising 10 CFR 2.101(a)(5) to allow COL applications to be submitted in two parts, with the environmental information submitted in one part and the remaining information submitted in a second part. Currently, 10 CFR 2.101(a)(5) may only be used in connection with applications for construction permits.

The staff is revising 10 CFR 2.340, "Initial Decision in Contested Proceedings on Applications for Facility Operating Licenses; Immediate Effectiveness of Initial Decision Directing Issuance of Amendment of Construction permit or Operating License," and making conforming changes throughout Part 2, to remove the restrictions currently in 10 CFR 2.340(f) and (g) regarding the immediate effectiveness of initial decisions in contested proceedings for nuclear power plants, as well as initial decisions in all other contested proceedings, such as specifically-licensed independent spent fuel storage installations, monitored retrievable storage, a high-level waste repository, and enforcement proceedings. The final rule also removes the "automatic stay for Commission review" provisions with respect to issuances of facility construction permits and operating licenses in the current rule, and does not include the March 2006 proposals to extend the "automatic stay" provisions to issuances of ESPs, combined licenses, manufacturing licenses, and to issuance of § 52.103(g) findings.

These restrictions, which were adopted after the 1979 accident at Three Mile Island, provide that the presiding officer's decision on a construction permit is not effective until the Commission reviews and acts on the decision. Consequently, there is an "automatic stay" of a presiding officer's decision on an operating license (other than a low-power license) pending Commission review. Under the final rule, the Director of either NRR or the Office of New Reactors (NRO), as appropriate, in a contested proceeding shall issue an LWA, construction permit, or license within 10 days of the issuance of a presiding officer's initial decision (1) if the Commission or the Director has otherwise made all necessary findings for issuance of the authorization, permit, or license; and (2) notwithstanding the pendency of a petition for reconsideration under 10 CFR 2.345 "Petition for Reconsideration," a petition for review under 10 CFR 2.341, "Review of Decision and Action of Presiding Officer," a motion for stay under 10 CFR 2.342, "Stays of Decisions," or a petition under 10 CFR 2.206, "Requests for Action under this Subpart." The final rule also authorizes the Commission or the appropriate Director in a contested proceeding to make the finding on ITAAC under 10 CFR 52.103(g) within 10 days of the issuance of a presiding officer's initial decision (1) if the Commission or the Director has made findings for all ITAAC which are not within the scope of the initial decision of the presiding officer; and (2) notwithstanding the pendency of a petition for reconsideration under 10 CFR 2.345, a petition for review under 10 CFR 2.241, a motion for stay under 10 CFR 2.342, or a petition under 10 CFR 2.206.

Finally, 10 CFR 2.104 is further revised from the proposed rule to add provisions addressing the nature of the Agency's adjudicatory inquiry in a COL hearing. First, the final rule makes clear that in a contested COL hearing, the Agency's adjudicatory review with respect to the *uncontested* matters is limited to those matters which must otherwise be addressed in an uncontested construction permit proceeding. Similarly, the final rule provides that in an

uncontested COL hearing, the overall Agency adjudicatory review is limited to those matters which must otherwise be addressed in an uncontested construction permit proceeding. Third, the final rule provides that where the COL references an ESP, the overall Agency adjudicatory review is further limited to those matters which must otherwise be addressed in an uncontested construction permit proceeding, but have not been addressed in the ESP. This represents a change from the March 2006 proposed rule, which essentially made no distinction with respect to the nature of the adjudicatory review in either an uncontested or contested COL hearing, or a COL hearing referencing an ESP.

COLs of Identical Design at Multiple Sites

Appendix N to 10 CFR Part 50 and 10 CFR Part 52 affords procedural benefits with respect to the application and hearing process for construction permit or operating license applicants who reference a common, "duplicate" design for their reactors. The March 2006 proposed rule would have removed Appendix N from 10 CFR Part 52. Upon reconsideration, the staff concluded that the Appendix N to 10 CFR Part 52 procedures would extend the "design-centered" review approach into the conduct of hearings on COLs referencing the same design. Therefore, the staff has restored Appendix N to 10 CFR Part 52, revised its title to reflect that it applies to applications referencing an "identical design," and made conforming changes to allow COL applicants to use its procedural provisions. The staff did make conforming changes to Subpart D of 10 CFR Part 2 to reflect the expanded scope of Appendix N to 10 CFR Part 52. The NRC may make these changes to the Agency's rules and practice and procedures in the final 10 CFR Part 52 rule without renoticing under the APA.

Resolution of Additional Issues

The resolution of the issues discussed in SECY-05-0203 can be found in the enclosed *Federal Register* notice. In addition, SECY-02-0180, "Legal and Financial Policy Issues Associated with Licensing New Nuclear Power Plants," dated October 7, 2002, identified two issues for future resolution that are related to the issuance of COLs. These issues are the delayed use of COLs, which includes banking of COLs, and the testing of new design features before issuance of a COL.

The staff has addressed all of the issues associated with requirements for testing of new design features in Section V.B of the final rule. The requirements for testing that are necessary to demonstrate the performance of new safety systems and components are set forth in the new 10 CFR 50.43(e). These new requirements also provide an option for an applicant to request approval to demonstrate the performance of new design features with a licensed prototype plant.

The issue of the delayed use of a COL was initially identified during discussions on licensing of multiple, modular (small) reactors. The Nuclear Energy Institute proposed that the NRC issue COLs for all of the modular reactors addressed in the application simultaneously even though construction may be delayed for many of the reactors for an indefinite time. As the staff stated in SECY-02-0180, this delayed use of COLs would be inconsistent with the Commission's policy on the duration of design approvals.

As a result of the Energy Policy Act of 2005, the 40-year period of operation under a COL will begin when the Commission makes its finding under 10 CFR 52.103(g) and the duration of the construction period, or the effective design approval for custom plants, would not be specified. Some of the prospective COL applicants have stated that they do not have definite plans to begin construction of their plant(s). Allowing a licensee to hold a COL for an indefinite time before beginning construction, would conflict with NRC's concept of the COL process and application of the backfit rule. NRC developed the COL process with the understanding that the licensee would begin construction upon receipt of the COL, which is consistent with past practice on issuance of construction permits. Also, in the past, NRC did not apply the backfit rule (10 CFR 50.109) until the operating license was issued. Under the revised 10 CFR 50.109, the backfit rule becomes applicable upon issuance of the COL. This change was made based on our understanding that design issues would be resolved before issuance of the COL and the licensee would begin construction upon receipt of the COL. With this understanding, 10 CFR 50.109 would protect the licensee during construction and during operation. The changes to the backfit rule were not intended to protect a licensee from new requirements during some indefinite time before the start of substantial construction.

The staff did not provide regulations in the final rule to address concerns with proposals to delay use of a COL. If the Commission is concerned about delays in initiation of construction by a particular applicant, it could either withhold issuance of the COL until the applicant is prepared to begin substantial construction or condition the COL to delay application of the backfit rule until the licensee has begun substantial construction.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the *Federal Register* the enclosed notice of final rulemaking (Enclosure 1).
2. Certify that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. Note that:
 - a. That staff has prepared a final regulatory analysis for this rulemaking (Enclosure 2).
 - b. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act of 1996 (5 U.S.C 804(2)) and has confirmed this determination with the Office of Management and Budget.
 - c. The proposed LWA rule, which has been provided to the Commission would, if adopted, further modify the final 10 CFR Part 52 rule.
 - d. The appropriate Congressional committees will be informed.

- e. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register.
- f. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). The Office of Management and Budget (OMB) has withheld approval of the information collection requirements until such time that public comments on these requirements and any changes made in response to those comments are submitted to the OMB. OMB review and approval must occur before publication of the final rule in the *Federal Register*.

RESOURCES:

To complete the rulemaking, 0.8 full-time equivalent (FTE) (.5 FTE for NRR and .3 FTE for OGC) is needed in the Fiscal Year (FY) 2007 and is included in the FY 2007 budget.

COORDINATION:

The Commission's January 30, 2006 SRM (ADAMS Accession No. ML060300640) directed the staff to provide the proposed final rule without review by the Committee to Review Generic Requirements (CRGR) and to seek feedback from the Advisory Committee on Reactor Safeguards (ACRS) on technical issues during the public comment period. Accordingly, the staff has provided an information copy of the final rule to the CRGR. The staff briefed the ACRS on the revised proposed rule for 10 CFR Part 52 on May 5, 2006, and received its feedback by letter on May 22, 2006 (ADAMS Accession No. ML061450310). OGC has no legal objection to this paper. The Office of the Chief Financial Officer has also reviewed this paper for resource implications and has no objections. In addition, the Office of Nuclear Security and Incident Response coordinated the changes related to offsite emergency preparedness with the Department of Homeland Security.

/RA William F. Kane Acting for/

Luis A. Reyes
Executive Director
for Operations

Enclosures:

1. *Federal Register* Notice
2. Regulatory Analysis
3. *Comment Summary Report:
10 CFR Part 52, Licenses,
Certifications, and Approvals
for Nuclear Power Plants*

NUCLEAR REGULATORY COMMISSION

**10 CFR Parts 1, 2, 10, 19, 20, 21, 25, 26, 50,
51, 52, 54, 55, 72, 73, 75, 95, 140, 170, and 171**

RIN 3150 - AG24

Licenses, Certifications, and Approvals for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations by revising the provisions applicable to the licensing and approval processes for nuclear power plants (*i.e.*, early site permit, standard design approval, standard design certification, combined license, and manufacturing license). These amendments clarify the applicability of various requirements to each of the licensing processes by making necessary conforming amendments throughout the NRC's regulations to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. The NRC has considered and resolved the public comments.

DATE: The effective date is **(Insert date 30 days after the date of publication)**

FOR FURTHER INFORMATION CONTACT: Nanette V. Gilles, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, telephone 301-415-1180, e-mail nvg@nrc.gov; or Jerry N. Wilson, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, telephone 301-415-3145, e-mail jnw@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background.
 - A. Development of Proposed Rule.

- B. Publication of Revised Proposed Rule.
- II. Overview of Public Comments.
- III. Reorganization of Part 52 and Conforming Changes in the NRC's Regulations.
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 - L. Changes to 10 CFR Part 26.
 - M. Changes to 10 CFR Part 51.
 - N. Changes to 10 CFR Part 54.
 - O. Changes to 10 CFR Part 55.
 - P. Changes to 10 CFR Part 72.
 - Q. Changes to 10 CFR Part 73.
 - R. Change to 10 CFR Part 75.
 - S. Changes to 10 CFR Part 95.
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 - V. Changes to 10 CFR Part 171.
- VI. Section-by-Section Analysis.
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- VIII. Agreement State Compatibility.
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- XII. Regulatory Analysis.
- XIII. Regulatory Flexibility Certification.
- XIV. Backfit Analysis.
- XV. Congressional Review Act.

I. Background.

A. Development of Proposed Rule.

On July 3, 2003 (68 FR 40026), the NRC published a proposed rulemaking that would clarify and/or correct miscellaneous parts of the NRC's regulations; update 10 CFR part 52 in its entirety; and incorporate stakeholder comments. On March 13, 2006 (71 FR 12781), the NRC issued a revised proposed rule that would rewrite part 52, make changes throughout the Commission's regulations to ensure that all licensing processes in part 52 are addressed, and clarify the applicability of various requirements to each of the processes in part 52 (*i.e.*, early site permit, standard design approval, standard design certification, combined license, and manufacturing license). This proposed rule superseded the July 3, 2003, proposed rule.

The NRC issued 10 CFR part 52 on April 18, 1989 (54 FR 15372), to reform the NRC's licensing process for future nuclear power plants. The rule added alternative licensing processes in 10 CFR part 52 for early site permits, standard design certifications, and combined licenses. These were additions to the two-step licensing process that already existed in 10 CFR part 50. The processes in 10 CFR part 52 allow for resolving safety and environmental issues early in licensing proceedings and were intended to enhance the safety and reliability of nuclear power plants through standardization. Subsequently, the NRC certified four nuclear power plant designs under subpart B of 10 CFR part 52—the U.S. Advanced Boiling Water Reactor (ABWR) (62 FR 25800; May 12, 1997), the System 80+ (62 FR 27840; May 21, 1997), the AP600 (64 FR 72002; December 23, 1999), and the AP1000 (71 FR 4464; January 27, 2006). These design certifications are codified in appendices A, B, C, and D of 10 CFR part 52, respectively.

The NRC planned to update 10 CFR part 52 after using the standard design certification process. The proposed rulemaking action began with the issuance of SECY-98-282, "Part 52 Rulemaking Plan," on December 4, 1998. The Commission issued a staff requirements memorandum (SRM) on January 14, 1999 (SRM on SECY-98-282), approving the NRC staff's plan for revising 10 CFR part 52. Subsequently, the NRC obtained considerable stakeholder

comment on its planned action, conducted three public meetings on the proposed rulemaking, and twice posted draft rule language on the NRC's rulemaking Web site before issuance of the July 2003 proposed rule.

B. Publication of Revised Proposed Rule.

A number of factors led the NRC to question whether the July 2003 proposed rule would meet the NRC's objective of improving the effectiveness of its processes for licensing future nuclear power plants. First, public comments identified several concerns about whether the proposed rule adequately addressed the relationship between part 50 and part 52, and whether it clearly specified the applicable regulatory requirements for each of the licensing and approval processes in part 52. In addition, as a result of the NRC staff's review of the first three early site permit applications, the staff gained additional insights into the early site permit process. The NRC also had the benefit of public meetings with external stakeholders on NRC staff guidance for the early site permit and combined license processes. As a result, the NRC decided that a substantial rewrite and expansion of the July 2003 proposed rulemaking was desirable so that the agency may more effectively and efficiently implement the licensing and approval processes for future nuclear power plants under part 52.

Accordingly, the Commission decided to revise the July 2003 proposed rule and published a revised proposed rule for public comment on March 13, 2006. This revised proposed rule contained a rewrite of part 52, as well as changes throughout the NRC's regulations, to ensure that all licensing and approval processes in part 52 are addressed, and to clarify the applicability of various requirements to each of the processes in part 52. In light of the substantial rewrite of the July 2003 proposed rule, the expansion of the scope of the

rulemaking, and the NRC's decision to publish the revised proposed rule for public comment, the NRC decided that developing responses to comments received on the July 2003 proposed rule would not be an effective use of agency resources. The NRC requested that commenters on the July 2003 proposed rule who believed that their earlier comments were not adequately addressed in the March 2006 proposed rule resubmit their comments.

II. Overview of Public Comments.

The public comment period for the March 2006 revised proposed rule expired on May 30, 2006. The NRC received 19 comment letters from industry stakeholders, other Federal agencies, and individuals during the public comment period. The NRC has considered and resolved all of the public comments received during the comment period and has made modifications to the rule language, as appropriate. The NRC has prepared a separate report, entitled *Comment Summary Report: 10 CFR Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants*, in which it summarizes the public comments received and discusses the agency's disposition of each comment. This report is available to the public as discussed in Section VII of the Supplementary Information of this document. The resolution of significant public comments is also discussed in Section IV, Responses to Specific Requests for Comments and, Section V, Discussion of Substantive Changes and Responses to Significant Comments in this document.

III. Reorganization of Part 52 and Conforming Changes in the NRC's Regulations.

Since the adoption of 10 CFR part 52 in 1989, the NRC and its external stakeholders identified a number of interrelated issues and concerns with the licensing process. One significant concern was that the overall regulatory relationship between part 50 and part 52 was not always clear. In the former rules, it was often difficult to tell whether general regulatory provisions in part 50 apply to part 52. One example is whether the absence of an exemption provision in part 52 denotes the NRC's determination that exemptions from part 52 requirements are not available, or that these exemptions are controlled by § 50.12. A related problem is the current lack of specific delineation of the applicability of NRC requirements throughout 10 CFR Chapter 1 to the licensing and approval processes in part 52. For example, the indemnity and insurance provisions in part 140 were not revised to address their applicability to applicants for and holders of combined licenses under subpart C of part 52. Even where part 52 provisions referenced specific requirements in part 50, it was not always clear from the language of the part 50 requirement how that requirement applied to the part 52 processes. For example, § 52.47(a)(1)(i) provides that a standard design certification application must contain the "technical information which is required of applicants for construction permits and operating licenses by 10 CFR...part 50...and which is technically relevant to the design and not site-specific."

The language did not explicitly identify the part 50 requirements that are "technically relevant to the design." Even where a specific regulation in part 50 is identified as a requirement, the language of the referenced regulation itself was not changed to reflect the specific requirements as applied to the part 52 processes. For example, § 52.79(b) provides that the application must contain the "technically relevant information required of applicants for an operating license required by 10 CFR 50.34." Other than the fact that this language shares the problem discussed earlier of what constitutes a "technically relevant" requirement, § 50.34(b) is based upon the two-step licensing process whereby certain important information

is submitted at the construction permit stage, and then supplemented with more detailed information at the operating license stage. Thus, it could be asserted that certain information that must be submitted in the construction permit application, *e.g.*, the “principal design criteria for the facility” required by § 50.34(a)(3)(i), may be regarded as not required to be submitted for a combined license application under the former version of part 52.

Another potential source of confusion is that the different subparts of part 52 and the appendices on standard design approvals and manufacturing licenses are not organized using the same format of individual sections (*e.g.*, “Scope of subpart,” followed by “Relationship to other subparts,” followed by “Filing of application”). Moreover, the organization and textual content of identically-titled sections differs among the subparts, and with appendices M, N, O, and Q, which establish additional licensing and approval processes. While these differences do not constitute an insurmountable problem to their use and application, it became apparent to the Commission that adoption of a common format, organization, and textual content would enhance usability and result in increased regulatory effectiveness and efficiency.

In the 2003 proposed rule, the NRC proposed several changes that were intended to address some (but not all) of these issues. However, based upon comments received on the 2003 proposed rule, the NRC’s experience to date with early site permit applications, interactions with external stakeholders concerning NRC guidance for combined license applications, and NRC’s screening of 10 CFR Chapter 1 requirements following the receipt of public comments on the 2003 proposed rule, the NRC concluded that the 2003 proposed rule would not adequately address and resolve these issues.

Accordingly, in the March 13, 2006, proposed rule the NRC took a more comprehensive approach to addressing these issues by reorganizing part 52, implementing a uniform format and content for each of the subparts in part 52, using consistent wording and organization of sections in each of the subparts, and making conforming changes throughout 10 CFR

Chapter 1 to reflect the licensing and approval processes in part 52. The NRC also coordinated and reconciled differences in wording among provisions in parts 2, 50, 51, and 52 to provide consistent terminology throughout all of the regulations affecting part 52. Under the NRC's reorganization of part 52, the existing appendices O and M on standard design approvals and manufacturing licenses, respectively, have been redesignated as new subparts in part 52. Redesignating these appendices as subparts in part 52 has resulted in a consistent format and organization of the requirements applicable to each of the licensing and approval processes. In addition, the redesignation clarifies that each of the licensing and approval processes in these appendices are available to potential applicants as an alternative to the processes in part 50 (construction permit and operating license) and the existing subparts A through C of part 52. The Commission does not, by virtue of this redesignation, either favor or disfavor the processes in the former appendices M and O of part 52. Rather, the Commission is standardizing the format and organization of part 52, and clarifying the full range of alternatives that are available under part 52 for use by potential applicants. Consistent with the broad scope of part 52, the NRC has retitled 10 CFR part 52 as "Licenses, Certifications, and Approvals for Nuclear Power Plants."

The NRC has also reorganized and expanded the scope of the administrative and general regulatory provisions that precede the part 52 subparts by adding new sections on written communications (analogous to § 50.4), employee protection (analogous to § 50.7), completeness and accuracy of information (analogous to § 50.9), exemptions (analogous to § 50.12), combining licenses (analogous to § 50.52), jurisdictional limits (analogous to § 50.53), and attacks and destructive acts (analogous to § 50.13). The NRC believes that adding the new sections to part 52 rather than revising the comparable sections in part 50 is more consistent with the general format and content of the Commission's regulations in each of the parts of Title 10.

Appendix N, which addresses duplicate design licenses, has been retained in both part 52 and part 50 to afford future applicants flexibility and to retain the possibility of achieving regulatory efficiencies in part 52 combined license proceedings. Since the preparation of the March 2006 proposed rule, several industry groups have announced their intention to seek combined licenses utilizing the same design. In view of this industry development, the NRC believes that there is potential utility to keeping the option of appendix N open to potential combined license applicants. Accordingly, the NRC is retaining in part 52 the procedural alternative provided in appendix N, and revising its language to make its provisions applicable to combined licenses using identical designs. Appendix Q, which addresses early staff review of site suitability issues, is also retained in part 50 and part 52. Appendix Q provides for NRC staff issuance of a staff site report on site suitability issues with respect to a specific site for which a potential applicant seeks the NRC staff's views. The staff site report is issued after receiving and considering the comments of Federal, State, and local agencies and interested persons, as well as the views of the Advisory Committee on Reactor Safeguards (ACRS), but only if site safety issues are raised. The staff site report does not bind the Commission or a presiding officer in any hearing under part 2. This process is separate from the early site permit process in subpart A of part 52. The NRC recognizes that there appears to be some redundancy between the early review of site suitability issues and the early site permit process. However, in order to allow early site permit and combined license applicants maximum flexibility in seeking early review of issues, the NRC has retained appendix Q to part 52 in the final rule. This is a change from the proposed rule, based largely on public comments in response to Question 3 in Section V of the Supplementary Information section of the proposed rule, where the NRC had proposed removing appendix Q from the Commission's regulations completely.

Inasmuch as the NRC may, in the future, adopt other regulatory processes for nuclear power plants, the NRC has reserved several subparts in part 52 to accommodate additional

licensing processes that may be adopted by the NRC. The NRC used a standard format and content for revising the regulations in the existing subparts and developing the new subparts that address the former appendices M and O. The standard format and content was modeled on the existing organization and content of subparts A and C. Appendices N and Q of part 52, however, have not been revised in that fashion because of time constraints in developing the final rule.

Perhaps most importantly, the NRC has reviewed the existing regulations in 10 CFR Chapter 1 to determine if the existing regulations must be modified to reflect the licensing and approval processes in part 52. First, the NRC determined whether an existing regulatory provision must, by virtue of a statutory requirement or regulatory necessity, be extended to address a part 52 process, and, if so, how the regulatory provision should apply. Second, in situations where the NRC has some discretion, the NRC determined whether there were policy or regulatory reasons to extend the existing regulations to each of the part 52 processes. Most of the conforming changes in this final rule occur in 10 CFR part 50. In making conforming changes involving 10 CFR part 50 provisions, the NRC has adopted the general principle of keeping the technical requirements in 10 CFR part 50 and maintaining all applicable procedural requirements in part 52. However, due to the complexity of some provisions in 10 CFR part 50 (e.g., § 50.34), this principle could not be universally followed. A description of, and bases for, the substantive conforming changes for each affected part is provided in Section V of this document.

To highlight the relationship between the requirements in part 52 of this final rule and the requirements in existing part 52, the NRC is making two cross-reference tables available to the public. These tables can be found on NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML062550246. Table 1 matches each part 52 requirement in this final rule with its counterpart in the existing rule. Table 2 is a reverse

cross-reference table which identifies the section of the existing part 52 requirements from which each part 52 requirement in this final rule was derived.

IV. Responses to Specific Requests for Comments.

In Section V of the Statements of Consideration for the March 13, 2006, proposed rule, the NRC posed 15 questions for which it solicited stakeholder comments. In the following paragraphs, these questions are restated, comments received from stakeholders are summarized, and the NRC resolution of the public comments is presented.

Question 1: General Provisions—Create new subpart for part 50. In response to several commenters' concerns about the clarity of the applicability of part 50 provisions to part 52, the Commission has added provisions to part 52 (§§ 52.0 through 52.11) that are analogues to comparable provisions in part 50. Another possible way of addressing the commenters' concerns would be to transfer all the provisions in part 52 to a new subpart (*e.g.*, subpart M) of part 50, and retain the existing numbering sequence for the current part 52 with the addition of a prefix (*e.g.*, proposed 50.1001 = current 52.1). The Commission is considering adopting this alternative proposal in the final rule and is interested in whether stakeholders regard this as a more desirable approach for minimizing the ambiguity of the relationship between part 50 and part 52.

Commenters' Response: Some commenters stated the clarity of the regulations would not be enhanced by moving provisions from part 52 to a new subpart of part 50. The commenters argued that in addition to not eliminating existing confusion, such a content shift

would create new confusion because current documents referencing part 52 would become “obsolete.”

NRC Response: The NRC has decided not to transfer provisions from part 52 to a new subpart in part 50, inasmuch as: (1) no commenter favored transferring provisions from part 52 to a new subpart in part 50, (2) either approach is legally equivalent, and (3) nearly 17 years has passed since the Commission adopted the approach of establishing early site permits, standard design certifications, and combined licenses in a new part 52, and a reorganization of the regulations at this time may engender confusion without any compensating benefits in clarity, regulatory stability and predictability, or efficiency.

Question 2: Currently, § 52.17(b) of subpart A of 10 CFR part 52 requires that an early site permit application identify physical characteristics that could pose a significant impediment to the development of emergency plans. An early site permit application may also propose major features of the emergency plans or propose complete and integrated emergency plans in accordance with the applicable standards of § 50.47 and the requirements of appendix E of 10 CFR part 50. The requirements in § 52.17 do not further define *major features of emergency plans*. Section 52.18 of subpart A requires the Commission to determine, after consultation with the Federal Emergency Management Agency, whether any major features of emergency plans submitted by the applicant under § 52.17(b) are acceptable. Section 52.18 does not provide any further explanation of the Commission’s criteria for judging the acceptability of major features of emergency plans.

The Commission has concluded, after undergoing the review of the first three early site permit applications, that the concept of Commission review and acceptance of major features of emergency plans may not achieve the same level of finality for emergency preparedness issues at the early site permit stage as that associated with a reasonable assurance finding of complete and integrated plans. Therefore, the Commission is considering modifying in the final

rule the early site permit process in proposed subpart A to remove the option for applicants to propose major features of emergency plans in early site permit applications and requests public comment on this alternative. The NRC believes that, if the option for early site permit applicants to include major features of emergency plans is to be retained, it would be useful to further define in the final rule what a major feature is and establish a clearer level of finality associated with the NRC's review and acceptance of major features of emergency plans. If the option to include major features of emergency plans is retained in the final rule, the NRC would define major features of emergency plans as follows:

Major features of the emergency plans means the aspects of those plans necessary to: (1) address one or more of the sixteen standards in § 50.47(b), and (2) describe the emergency planning zones as required in §§ 50.33(g), 50.47(c)(2), and appendix E to 10 CFR part 50.

In addition, the NRC is considering adopting in the final rule the requirement that major features of emergency plans must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC's regulations, insofar as they relate to the major features under review.

The NRC believes that, under this alternative, the level of finality associated with each major feature that the Commission found acceptable would be equivalent, for that individual major feature, to the level of finality associated with a reasonable assurance finding by the NRC for a complete and integrated plan, including inspections, tests, analyses, and acceptance criteria (ITAAC), at the early site permit stage.

Commenters' Response: Several commenters suggested the current process for addressing major features of emergency plans (EP) in the early site permit (ESP) be retained without modification. Some commenters expressed a fear that the loss of this option would result in a loss of flexibility to achieve “finality” without producing a comprehensive EP. Some commenters identified a need to clarify the definition of “major features” of the EP to make it less restrictive. Some commenters believed that the approved major features were acceptable elements of a “complete and integrated emergency plan that would be considered later.” Some commenters believed the information should not be reviewed again during the COL process, which would instead focus on (1) the integration of these major features with information necessary to support the “reasonable assurance finding,” and (2) the updating of EP information required by § 52.39 (b).

NRC Response: Based on the commenters' feedback, the NRC has decided to retain the current process for addressing major features of emergency plans in an ESP without modification. The NRC agrees that it should clarify the definition of “major features” and has done so by adding the definition suggested by the commenters to § 52.1 in the final rule. For a detailed discussion of the basis for this change, see Section V.C.5.b of the Supplementary Information section of this notice which discusses changes to § 52.1, “Definitions.”

Question 3: As indicated in Section IV, *Discussion of Substantive Changes* (in the March 13, 2006, proposed rule), the NRC is proposing to remove appendix Q to part 52 entirely from part 52 and retain it in part 50. Currently, appendix Q to part 52 provides for NRC staff issuance of a staff site report on site suitability issues with respect to a specific site, for which a person (most likely a potential applicant for a construction permit or combined license) seeks the NRC staff's views. The NRC is also considering removing, in the final rule, the early site review process in appendix Q to part 52 in its entirety from the NRC's regulations and is interested in stakeholder feedback on this alternative. One possible reason for removing the

early site review process in its entirety is that potential nuclear power plant applicants would use the early site permit process in subpart A of part 52, rather than the early site review process as it currently exists in appendix Q to parts 50 and 52. Also, in cases where a combined license applicant was interested in seeking NRC staff review of selected site suitability issues (as appendix Q to part 52 was designed for), the applicant could request a pre-application review of these issues. The use of pre-application reviews for selected issues has been successfully used by applicants for design certification. The NRC is especially interested in the views of potential applicants for nuclear power plant construction permits and combined licenses as to whether there is any value in retaining the early site review process.

Commenters' Response: Some commenters expressed concern about the loss of flexibility to assess site suitability that would result from the deletion of appendix Q from parts 50 and 52. These commenters believed that appendix Q to parts 50 and 52 (in conjunction with subpart F of 10 CFR part 2) was important for allowing "critical path issues" to be reviewed prior to submission of a combined license (COL) application in instances where prior completion of an ESP was not feasible. Some commenters argued for the efficiency of appendix Q to parts 50 and 52 and subpart F of part 2 because only applicant-selected issues would be reviewed during these processes. Some commenters recommended changes be made to specifically allow ESP and COL applicants to reference an early site review conducted in accordance with appendix Q or subpart F. The commenters stated that the NRC should not delete the option for a part 52 applicant to reference a review performed under appendix Q to 10 CFR part 52.

NRC Response: The NRC has decided not to remove appendix Q from part 50 or part 52 in the final rule. Appendix Q has been included in part 52 in the final rule and conforming changes have been made to make it available for use by prospective early site permit and combined license applicants. Such applicants will have the same option for early

resolution of site suitability issues as is currently available to construction permit applicants. This will provide early site permit and combined license applicants with additional flexibility to seek early resolution of issues.

The NRC also agrees that § 2.101(a-1) and subpart F of part 2 should be modified to allow applicants for early site permits and combined licenses under part 52 to take advantage of those provisions. Both § 2.101(a-1) and subpart F of part 2 have been revised in the final rule, albeit somewhat differently than the approach recommended by the commenter. Inasmuch as the revisions are to the Commission's rules of procedure and practice, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

Question 4: Under subpart F of part 52 of the proposed rule, the NRC proposes to require approval of, and extend finality to, the final design for a reactor to be manufactured under a manufacturing license. While the NRC will also review the acceptability of the manufacturing license applicant's organization responsible for design and manufacturing, as well as the quality assurance (QA) program for design and manufacturing, the proposed rule does not provide a regulatory structure for further extending the scope of NRC review and issue finality to the manufacturing process itself. The NRC is considering extending regulatory review approval, and consequently expand issue finality, to the manufacturing itself in the final rule. There are two models that the Commission is considering adopting if it were to move in this direction. The first would be an analogue to the subpart C of part 52 combined license process, whereby the NRC would review and approve manufacturing ITAAC to be included in the manufacturing license. During the manufacturing of each reactor, the NRC would verify at the manufacturing location whether the ITAAC have been conducted and the acceptance criteria met. A NRC finding of successful completion of all the ITAAC would preclude any further inspection of the acceptability of the manufacture of the reactor at the site where the

manufactured reactor is to be permanently sited and operated. The NRC's inspections and findings for the combined license or operating license would be limited to whether the reactor had been emplaced in undamaged condition (or damage had been appropriately repaired) and all interface requirements specified in the manufacturing license had been met. The NRC believes that it has authority to issue a manufacturing license under Section 161.h of the AEA.

The other model that the NRC could adopt would be a combination of the approval processes used by the Federal Communications Commission (FCC) and Federal Aviation Administration (FAA) in approving the manufacture of electronic devices and airplanes. The NRC's manufacturing license would approve: (1) the design of the nuclear power reactor to be manufactured; (2) the specific manufacturing and quality assurance/quality control processes and procedures to be used during manufacture; and (3) tests and acceptance criteria for demonstrating that the reactor has been properly manufactured. To be completely consistent with the FCC and FAA models, the NRC would issue a manufacturing license only after a prototype of the reactor had been constructed and tested to demonstrate that all performance requirements (*i.e.*, compliance with NRC requirements and manufacturer's specifications) can be met by the design to be approved for manufacture.

The NRC requests public comment on whether the manufacturing license process in proposed subpart F of part 52 should be further extended in the final rule to provide an option for NRC approval of the manufacturing, and if so, which model of regulatory oversight, *i.e.*, the combined license ITAAC model or the FCC/FAA approval model, should be used by the NRC. The NRC also seeks public comment on whether an opportunity for hearing is required by the AEA in connection with a NRC determination that the manufacturing ITAAC have been successfully completed.

Commenters' Response: Some commenters requested that applicants for manufacturing licenses be allowed, but not required, to use ITAAC to ensure that an "as-

manufactured plant conforms to the important design characteristics specified in the application for the manufacturing license.” Some commenters stated that a manufacturing license for evolutionary designs should be subject to proposed § 50.43(e) and should not require a prototype. Some commenters stated that manufacturing licenses should not be subject to more stringent requirements than design certifications.

NRC Response: The NRC has decided to defer consideration of this alternative on ITAAC, for several reasons. First, one commenter’s proposal to allow ITAAC for assuring that the as-manufactured reactor “conforms to the important design characteristics specified in the application for the manufacturing license,” raises questions about what those “important design characteristics” might be, and why the ITAAC would be so narrowly limited. The Commission did not receive any in-depth comments presenting arguments one way or the other on the feasibility of developing such ITAAC, and the potential legal implications of, and technical considerations with respect to, such a finding by the manufacturer. Moreover, it is clear that any regulatory process that the Commission may adopt in rulemaking would require further opportunity for public comment, and therefore could not be adopted in a final part 52 rulemaking without substantial delay. In light of the lack of any near-term interest by any entity in obtaining a manufacturing license, the Commission has decided not to adopt any provisions for ITAAC governing approval of manufacturing in the final part 52 rule. However, the Commission would address these issues in a timely fashion if raised in a rulemaking petition which demonstrated near-term interest in an application for a manufacturing license.

The Commission agrees with the commenters’ suggestions that manufacturing licenses for evolutionary designs should be subject to new § 50.43(e), and that under those provisions a prototype would not be prerequisite to issuance of a manufacturing license for an evolutionary design. Further discussion is provided below in *Testing Requirements for Advanced Reactors*.

Question 5: Currently, part 52 allows an applicant for a construction permit to reference either an early site permit under subpart A of part 52 or a design certification (DC) under subpart B of part 52. Specifically, § 52.11 states that subpart A of part 52 sets out the requirements and procedures applicable to NRC issuance of early site permits for approval of a site or sites for one or more nuclear power facilities separate from the filing of an application for a construction permit or combined license for such a facility. Similarly, § 52.41 states that subpart B of part 52 sets out the requirements and procedures applicable to NRC issuance of regulations granting standard design certification for nuclear power facilities separate from the filing of an application for a construction permit or combined license for the facility. However, the current regulations in 10 CFR part 50 that address the application for and granting of construction permits do not make any reference to a construction permit applicant's ability to reference either an early site permit or a design certification. Also, the NRC has not developed any guidance on how the construction permit process would incorporate an early site permit or design certification, nor has the nuclear power industry made any proposals for the development of industry guidance on this subject. The NRC has not received any information from potential applicants stating an intention to seek a construction permit for the construction of a future nuclear power plant. In addition, the NRC recommends that future applicants who want to construct and operate a commercial nuclear power facility use the combined license process in subpart C of part 52. Therefore, the NRC is considering removing from part 52, in the final rule, the provisions allowing a construction permit applicant to reference an early site permit or a design certification and is interested in stakeholder feedback on this alternative.

Commenters Response: Some commenters stated the deletion of provisions allowing a construction permit applicant to reference an ESP or DC was ill-advised given the untested nature of the COL process and the resulting need to retain "regulatory flexibility" to deal with unexpected issues. As a contingency plan to buffer against difficulties with COL process, the

commenters proposed the addition of a provision in part 50 to specify that a construction permit applicant could reference a DC without the inclusion of ITAAC. The commenters suggested that in these instances, “the operating license proceeding would need to find under 10 CFR 50.57(a)(1) that construction of the facility has been substantially completed, in conformity with the construction permit and the application as amended, the provisions of the Act, and the rules and regulations of the Commission.” Commenters stated that standard design should be final and not open to review in the construction permit and operating licenses proceeding. Commenters requested a construction permit applicant be able to reference an ESP in the same way as would a COL applicant.

NRC Response: Based on some of the commenters’ responses to this question and further consideration of the issue, the NRC has decided not to make any changes in the final rule to delete provisions allowing a construction permit applicant to reference an early site permit or a design certification. The NRC has also decided not to add any additional provisions to part 50 or part 52 to address a construction permit applicant’s ability to reference either a design certification or an early site permit. The NRC believes it is unlikely that such a construction permit application will be submitted and the NRC will handle any such applications on a case-by-case basis. If such an application were submitted, there are many process issues that would need to be carefully considered and would need to be discussed with the applicant and other stakeholders. In particular, the previously certified designs all used design acceptance criteria in lieu of detailed design information. A process for completing that design information without using ITAAC would have to be developed.

Question 6: The NRC is considering revising § 52.103(a) in the final rule to require the combined license holder to notify the NRC of the licensee’s scheduled date for loading of fuel into a plant no later than 270 days before the scheduled date, and to advise the NRC every 30 days thereafter if the date has changed and if so, the revised scheduled date for loading of fuel.

The initial notification would facilitate timely NRC publication of the notice required under § 52.103(a) and NRC staff scheduling of inspection and audit activities to support NRC staff determinations of the successful completion of ITAAC under § 52.99. The proposed updating would also facilitate NRC staff scheduling of those inspection and audit activities, Commission completion of hearings within the time frame allotted under § 52.103(e), and any Commission determinations on petitions as provided under § 52.103(f). The NRC requests public comment on the benefits and impacts (including information collection and reporting burdens) that would occur if the proposed requirements were adopted.

Commenters' Response: Some commenters agreed with this concept. However, they do not support a rule change because they believe a rule change is not necessary. Rather, they believe that the concept should be implemented via guidance rather than a rule change. Additionally, following the initial notification, a licensee should be required to submit a follow-up 30-day notification only if the schedule in the prior notification has changed. It would be unnecessarily burdensome to require a licensee to submit notifications every 30 days stating that the schedule has not changed.

NRC Response: The NRC has decided to amend § 52.103(a) in the final rule to ensure that the combined license holder will notify the NRC of its scheduled date for initial loading of fuel into a plant no later than 270 days before the scheduled date, and will notify the NRC of updates to its schedule every 30 days thereafter. The notification will facilitate timely NRC publication of the notice required under § 52.103(a), completion of hearings within the time frame allotted under § 52.103(e), and completion of any Commission determinations on petitions filed under § 52.103(f). The NRC believes that the update notifications when the schedule has not changed will not be burdensome. Additional discussion on this issue is provided in Section V.C.8.b of the supplementary information in this final rule.

Question 7: As discussed in Section IV.C.6.f of the March 13, 2006, proposed rule, the NRC is proposing to modify § 52.79(a) to add requirements for descriptions of operational programs that need to be included in the final safety analysis report (FSAR) to allow a reasonable assurance finding of acceptability. This proposed amendment is in support of the Commission's direction to the staff in SRM-SECY-02-0067 dated September 11, 2002, "Inspections, Tests, Analyses, and Acceptance Criteria for Operational Programs (Programmatic ITAAC)," that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application. In this SRM, the Commission stated:

[a]n ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage. The burden is on the applicant to provide the necessary and sufficient programmatic information for approval of the COL without ITAAC.

Accordingly, the NRC is proposing in the final part 52 rulemaking to add requirements to § 52.79 that combined license applications contain descriptions of operational programs. In doing so, the Commission has taken into account NEI's proposal to address SRM-SECY-04-0032 in its letter dated August 31, 2005 (ML052510037). However, the NRC is concerned that there may be operational program requirements that it has not captured in its proposed § 52.79. Therefore, the NRC is requesting public comment on whether there are additional required operational programs that should be described in a combined license application that are not identified in proposed § 52.79. If additional required operational programs are identified, the Commission is considering adding them to § 52.79 in the final rule.

Commenters Response: Some commenters believed that requirements for operational programs were sufficient as proposed, and that no additional operational programs needed to be described in the COL application.

NRC Response: The NRC does not agree that no additional operational programs need to be described in a COL application. During the preparation of the final rule, the NRC discovered that several of the operational programs listed in SECY-05-0197 (October 28, 2005) were not addressed in proposed § 52.79. To ensure the list of requirements for the contents of applications is complete, the NRC is adding several new provisions to address operational programs in the final rule. Specifically, the NRC is adding requirements to § 52.79 for COL applicants to include a description of: (1) the process and effluent monitoring and sampling program required by appendix I to 10 CFR part 50 [§ 52.79(a)(16)(ii)]; (2) a training and qualification plan in accordance with the criteria set forth in appendix B to 10 CFR part 73 [§ 52.79(a)(36)(ii)]; (3) a description of the radiation protection program required by § 20.1101 [§ 52.79(a)(39)]; (4) a description of the fire protection program required by § 50.48 [§ 52.79(a)(40)]; and (5) a description of the fitness-for-duty program required by 10 CFR part 26 [§ 52.79(a)(44)]. During the preparation of the final rule, the NRC also noticed that it had not completely implemented the Commission's direction regarding the treatment of operational programs in a COL application because it had failed to add requirements to address program implementation in its revisions to § 52.79(a). Therefore, in the final rule, the NRC has added requirements to address the implementation of all operational programs required to be described in a COL application. This is consistent with the Commission's direction to the staff in SRM-SECY-02-0067 (September 11, 2002, ML022540755) that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application.

Question 8: Backfitting—reproduce backfitting requirements in part 52. The NRC notes that the backfitting provisions applicable to various part 52 processes are contained in both part 50 and part 52 and, therefore, the proposed language for § 50.109 cross-references to applicable provisions of part 52, which may be confusing. The NRC is considering adopting in the final rule an alternative which would remove from § 50.109 the backfitting provisions applicable to the licensing and approval processes in part 52, and place them in part 52. There are two possible approaches for doing so: the first would be for the NRC to establish a general backfitting provision in part 52 applicable exclusively to the licensing and approval processes in part 52. Under this approach, each licensing and approval process in part 52 would be the subject of a backfitting section in a new subpart of part 52 (e.g., § 52.201 for standard design approvals, etc.). The existing backfitting provisions applicable to early site permits and design certification would be transferred to the relevant sections in the new subpart. The second approach would be to ensure that each subpart of part 52 contains the backfitting provisions applicable to the licensing or approval process in that subpart. The NRC is considering adopting these alternative approaches in the final rule and requests public comment on whether either of these administrative approaches is preferable to the approach in the proposed rule.

Commenters' Response: Some commenters stated that NRC's alternative approach to addressing backfitting was unnecessary to clarify the application of the backfit rule to part 52 actions. Commenters stated that the proposed rule included adequate references to § 50.109 and in the various subparts of part 52, making replication of this language elsewhere unnecessary. If the NRC deemed the inclusion of such information necessary, several commenters suggested each subpart in part 52 include its own standards for backfitting to avoid confusion.

NRC Response: The NRC has decided to revise § 50.109 to include the conforming changes necessary to reflect part 52, rather than adopting a backfitting provision in part 52,

because no commenter favored the alternative approach of adopting a backfitting provision in part 52, and both approaches are legally equivalent.

Question 9: The Commission is considering adopting in the final part 52 rulemaking an alternative to the re-proposed rule's approach for addressing new and significant environmental information with respect to matters addressed in the ESP environmental impact statement (EIS) which require supplementation.¹ As a separate matter, the Commission is also considering adopting in the final part 52 rulemaking an analogous requirement for addressing new information necessary to update and correct the emergency plan approved by the ESP, the ITAAC associated with EP, or the terms and conditions of the ESP with respect to emergency preparedness, or new information materially changing the Commission's determinations on emergency preparedness matters previously resolved in the ESP. To implement either or both of these alternatives, the Commission is also evaluating whether several additional concepts should be adopted in the final rulemaking. The two alternatives, as well as the additional implementing concepts, are described below. The Commission emphasizes that it may, with respect to the alternative addressing updating environmental information and emergency preparedness information, adopt either or both alternatives in the final part 52 rulemaking, in place of or in addition to the proposed rule's alternative of conducting the updating in each combined license proceeding. Under the option where multiple alternatives for updating environmental and emergency preparedness information would be allowed, the Commission proposes that the decision be left to the combined license applicant as to which alternative to pursue. Commenters are requested to address: (1) the advantages and disadvantages of adopting each alternative for updating environmental and emergency preparedness information

¹The scope of environmental information that must be supplemented is limited to the matters which were addressed in the original EIS for the ESP. Thus, for example, if the ESP applicant chose not to address need for power (as is allowed under § 52.18), the combined license applicant need not address need for power in its environmental report (ER) to update the ESP EIS, and the NRC need not determine whether there is new and significant information with respect to need for power as part of the updating of the ESP EIS.

in an ESP proceeding as opposed to the proposed rule's alternative of conducting the updating in each combined license proceeding; (2) whether the Commission should only allow updating of environmental and emergency preparedness information in an ESP proceeding or in a COL proceeding, but not both; and (3) if the Commission allows updating in either an ESP proceeding or in a COL proceeding, whether it should be an option for the COL applicant to decide which update process to pursue. The Commission believes it may allow COL applicants the option of deciding whether to update environmental and emergency preparedness information in either an ESP proceeding or in a COL proceeding in order to afford the COL applicant the determination which approach best satisfies their business and economic interests.

Environmental matters resolved in ESP

The Commission is considering requiring a combined license applicant planning to reference an ESP to submit a supplemental environmental report for the ESP. The supplemental environmental report must address whether there is any new and significant environmental information with respect to the environmental matters addressed in the ESP EIS. Based upon this information, the NRC will prepare a draft supplemental environmental assessment (EA) or EIS setting forth the agency's proposed determinations with respect to any new and significant information. In accordance with existing practice and procedure, the draft supplemental EA or EIS will be issued for public comment. After considering comments received from the public and relevant Federal and State agencies, the NRC will issue a final supplemental EA or EIS. Once the final supplemental EA or EIS is issued, the ESP finality provisions in proposed § 52.39 would apply to the matters addressed in the supplemental EA or EIS, and those matters need not be addressed in any combined license proceeding referencing the ESP. Thus, for example, if a new and significant environmental issue, for example, a newly-designated endangered species, is addressed in the supplemental ESP EIS, the matter

would be resolved for all combined licenses referencing the ESP (unless, of course, there is new and significant information identified at the time of a subsequent referencing combined license with respect to that endangered species). There would be no updating of environmental information necessary in the combined license proceeding. The Commission considers this approach for updating the ESP as meeting the Agency's obligations under the National Environmental Policy Act (NEPA), without imposing undue burden on the ESP holder and the NRC through continuous or periodic updating, and preserving the distinction between the ESP and any referencing combined license proceeding. Since an ESP may be referenced more than once, this approach would provide for issue finality of the updated information and preclude the need for reconsideration of the same environmental issue in successive combined license proceedings referencing the ESP. The Commission requests public comment on this proposal, which would likely involve changes to §§ 52.39, 51.50(c), 51.75, and 51.107 (and possibly conforming changes in parts 2, 51, and 52).

Emergency preparedness information resolved in ESP

The Commission is separately considering requiring a combined license applicant referencing an ESP to provide to the NRC new EP information necessary to correct inaccurate information in the ESP emergency plan, EP ITAAC, or the terms and conditions of the ESP with respect to EP. Based upon the EP information submitted by the combined license applicant, the NRC will, as necessary, approve changes to the ESP emergency plan, the EP ITAAC, or the terms and conditions of the ESP with respect to EP. Once the Commission has resolved the EP updating matters, these matters would be accorded finality under § 52.39. There would be no separate updating necessary in the combined license proceeding. Thus, for example, if an EP ITAAC in an ESP were changed by virtue of this updating process, the changed ITAAC for EP would be applicable to any combined license referencing the ESP whose ITAAC have not yet been satisfied (*i.e.*, the amended EP ITAAC would not be applicable to a combined

license where the Commission has made the § 52.103(g) finding with respect to that EP (ITAAC). The NRC's consideration of such EP information would be considered to be part of the ESP proceeding, and any necessary changes with respect to EP would therefore be deemed to be changes within the scope of the ESP. The Commission considers this proposal as a means for updating the ESP with respect to EP information in a timely fashion, without imposing undue burden on the ESP holder and the NRC through continuous or periodic updating, while preserving the distinction between the ESP and any referencing combined license proceeding.

Since an ESP may be referenced more than once, this approach would provide for issue finality of the updated information and preclude the need for reconsideration of the same issue in successive combined license proceedings referencing the ESP. The Commission requests comment whether this approach should be adopted by the Commission in the final rulemaking, which will likely involve changes to § 52.39 (and possible conforming changes in § 50.47, 50.54, and 10 CFR part 50, appendix E).

ESP updating in advance of combined license application submission

To minimize the possibility that the ESP updating process may adversely affect a combined license proceeding referencing that ESP, the Commission proposes to require the combined license applicant intending to reference an ESP to submit its application to update the ESP with respect to EP and/or environmental information no later than 18 months before the submission of its combined license application. The Commission believes that the 18-month lead time is sufficient to complete the NRC's regulatory consideration of the updating, such that the combined license applicant will be able to prepare its application to reflect the updated ESP. The Commission also recognizes that there may be increased regulatory complexity under this approach, as well as the possibility that resources may be unnecessarily expended if the potential combined license applicant ultimately decides not to proceed with its application. The Commission requests public comment on whether the 18-month lead time is

appropriate, whether the time should be decreased or increased, or whether the Commission should simply require that the ESP update application be filed no later than simultaneously with the filing of the combined license application. Based upon the public comments, the Commission will adopt one of these alternatives, if it decides that updating of environmental and/or EP matters should be accomplished in an ESP proceeding, as opposed to the combined license proceeding in which the ESP is referenced.

Expanding the scope of resolved issues after ESP issuance

The Commission is also considering whether the final rule should include provisions addressing how the ESP holder may request, at any time after the issuance of the ESP, that additional issues be resolved and given finality under § 52.39. For example, the holder of the ESP which does not include an approved emergency plan, may wish to submit complete emergency plans for NRC review and approval. Such a request is not explicitly addressed in either the current or re-proposed subpart A to part 52, although it would be reasonable to treat that request as an application to amend the ESP.

The Commission requests public comment on whether the Commission should adopt in the final rule new provisions in subpart A to part 52 that would explicitly address requests by the ESP holder to amend the early site permit to expand the scope of issues which are resolved and given issue finality under § 52.39. The Commission is also considering whether, as part of the ESP updating process discussed previously, the ESP holder/combined license applicant should be allowed to request an expansion of issues which are resolved and given issue finality.

If the Commission were to allow an ESP holder/combined license applicant to expand the scope of resolved issues in the ESP update proceeding, the Commission believes that the 18-month time period for filing the updating application in the ESP proceeding may be insufficient, and is considering adopting in the final rule a 24-month (2-year) period for filing the ESP updating application, where the ESP holder/combined license applicant seeks to expand

the scope of resolved issues. The Commission seeks public comment on whether, in such cases, the Commission should require in the final rule an 18- or 24-month period, or some other period, for submitting its ESP updating application.

Approval in ESP of process and criteria for updating ESP after issuance

The Commission requests public comment whether the Commission should adopt in the final rulemaking provisions affording the ESP applicant the option of requesting NRC approval of procedures and criteria for identifying and assessing new and significant environmental information, and/or new information necessary to update and correct the emergency plan approved by the ESP, the ITAAC associated with emergency preparedness (EP), or the terms and conditions of the ESP with respect to emergency preparedness, or otherwise materially changing the Commission's determinations on emergency preparedness matters previously resolved in the ESP. These procedures and criteria, if approved as part of the ESP issuance, could be used by any combined license applicant referencing the ESP to identify the need to update the ESP with respect to environmental and/or emergency preparedness information. There would be no need for the NRC to review the adequacy of the ESP holder/combined license applicant's process and criteria for determining whether new information is of such importance or significance so as to require updating; the NRC review could thereby be focused solely on whether the ESP holder's updated information, or determination that there is no change in either an environmental or emergency preparedness matter, was correct and adequate. Under this proposal, § 52.17 and/or § 51.50(b) would be amended to incorporate such a process for "pre-approval" of ESP updating procedures and criteria.

While NRC approval of updating procedures and criteria would be reflected in the ESP, the Commission does not believe that the ESP itself must contain the procedures and criteria in order to be accorded finality under § 52.39. An ESP holder/combined license applicant need not comply with any or all of the updating process and criteria, and would be free to use (and

justify) other procedures or criteria in the ESP updating proceeding. Naturally, there would be no finality associated with such departures from the ESP-approved procedures and criteria.

The Commission does not believe that either subpart A of part 52 or an ESP with the contemplated approved updating procedures and criteria should contain a “change process” akin to § 50.59, allowing the ESP holder to make changes to the approved updating procedures and criteria without NRC review and approval. Any change (other than typographic and administrative corrections) should require an amendment to the ESP. However, the Commission seeks public comment on whether a different course should be adopted in the final rule.

The Commission recognizes that any NRC-approved procedures and criteria for updating environmental and/or emergency preparedness information in an ESP updating process as described previously, would be equally valid for updating such information under the updating provisions in the re-proposed rule. The Commission requests comments on whether, if the Commission adopts in the final rulemaking the re-proposed rule’s concept of updating in the combined license proceeding, the Commission should provide the ESP applicant with the option of seeking NRC approval of the procedures and criteria for updating environmental and/or emergency preparedness information in a combined license proceeding which references the ESP.

Public participation in ESP updating process

The Commission is considering two ways for allowing public participation in the updating process, if the updating alternative is adopted in the final rule. One approach would be to allow interested persons to challenge the proposed updating by submitting a petition, analogous to that in proposed § 52.39(c)(2), which would be processed in accordance with § 2.206. This approach would be most consistent with the existing provisions in § 52.39, inasmuch as updating of an ESP is roughly equivalent to a request that the terms and conditions of an ESP

be modified. A consequence of this approach is that the potential scope of matters which may be raised is not limited to those ESP matters which the ESP holder/combined license applicant and the NRC conclude must be updated.

The other approach that the Commission may adopt is to treat any necessary updating as an amendment to the ESP, for which an opportunity to request a hearing is provided. This approach would limit the scope of the hearing to those matters for which an amendment is required. Where the ESP holder does not request an amendment on the basis that no updating is necessary with respect to a matter, an interested person could not intervene with respect to that matter. A consequence of this approach is that, under the Commission's regulations in 10 CFR part 2 and its current practice, a hearing granted on any amendment necessitated by the updating process would be more formalized than a hearing accorded under the § 2.206 petition process. The Commission requests public comment on the approach that the Commission should adopt, together with the reasons for the commenter's recommendation.

Commenter Response: Several commenters believed an ESP holder should not be required to update the information in the ESP application. These commenters stated that the proposal to require updating would add an unnecessary additional level of review (and possibly hearings) with little or no additional benefit (*i.e.*, the COL applicant would still be under the obligation to update the information provided by the ESP holder). Some commenters contended that an updating requirement would only serve to erode the finality and certainty provided by the ESP, thereby defeating one of the purposes of an ESP. These commenters also believed that an updated requirement would run counter to NRC regulations. Some commenters stated that while the ESP is in effect, the NRC cannot change or impose new requirements, including emergency planning requirements, unless it determines that a modification is necessary either to bring the permit or the site into compliance with the NRC's regulations and orders applicable and in effect at the time the permit was issued, or to assure

adequate protection of the public health and safety or the common defense and security. Commenters argued that the proposed 18-month updating requirement may not be feasible. A commenter gave the following example, “under the NRC’s current schedule for the existing ESP applications for North Anna and Grand Gulf, the ESPs will not be issued until 2007, shortly before the planned COL applications for those sites. This would result in insufficient time for the updating envisioned by the NRC, and it would be unfair to those applicants to require them to delay their COL applications to accommodate the updating process. Additionally, the proposed updating process would be inconsistent with 10 CFR § 52.27(c), which permits a COL application to reference an ESP application.”

Several commenters agreed with NRC’s proposal to provide the ESP holder with the option of requesting an ESP amendment in order to resolve issues that were not addressed at the ESP stage or to achieve finality on updated information. These commenters also suggested that a COL applicant should be able to reference an application for an ESP amendment that is pending approval by the NRC similar to the process that already exists in 10 CFR 52.27(c).

Several commenters expressed the belief that a COL applicant should be able to make changes or updates to ESP emergency planning information without NRC approval in accordance with the criteria in 10 CFR 50.54(q) just as the remaining safety information can be revised under § 50.59 once it has been reviewed and approved. These commenters also stated that this revised information should not be considered as an “amendment” submitted under § 50.90 for review and approval, but rather should be considered to be information equivalent to that provided under § 50.71(e) for information.

NRC Response: Upon consideration of the public comments on this subject, the NRC has decided not to require updating of ESP information prior to receipt of a COL application referencing the ESP. The NRC is retaining the proposed rule structure for dealing with new EP

and environmental information at the COL stage. The NRC believes this structure will provide for the most effective and efficient use of NRC and applicant resources. The NRC is, however, making revisions to the final rule to allow for voluntary changes to an ESP by the ESP holder through the license amendment process. Specifically, the NRC is making revisions to §§ 50.90 and 50.92 to include ESPs within the scope of these requirements. The NRC is also adding a new provision to § 52.39 to allow ESP holders to make changes to the ESP, including changes to the SSAR, under the license amendment process. These changes will provide ESP holders with additional flexibility to resolve issues that were not addressed in the original ESP review and to achieve finality on new information. The NRC does not believe it is necessary to add rule language to address the situation where a COL applicant references an ESP for which there is an amendment review pending before the NRC. The NRC will address these situations on a case-by-case basis.

Question 10: The Commission is considering adopting in the final part 52 rulemaking a new provision in § 50.71 that would require combined license holders to update the PRA [probabilistic risk assessment] submitted with the combined license application periodically throughout the life of the facility on a schedule similar to the schedule for final safety analysis report (FSAR) updates (*i.e.*, at least every 24 months) or, alternatively, on a schedule to coincide with every other refueling outage. Updates would be required to ensure that the information included in the PRA contains the latest information developed. The PRA update submittal would be required to contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the original PRA, or as appropriate, the last update to the PRA under this section. The submittal would be required to include the effects of all changes made in the facility or procedures as reflected in the PRA; all safety analyses and evaluations performed by the licensee either in support of approved license amendments or in

support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) or, in the case of a license that references a certified design, in accordance with § 52.98(c); and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The Commission requests stakeholder feedback on whether such a requirement should be added to the Commission's regulations and, if so, what is an appropriate update schedule.

Commenters Response: Several commenters noted that the proposed rule did not include a frequency for updating the PRA. These commenters noted that the Commission stated that PRA scope and methods should be addressed in guidance, not in regulations (SRM on SECY-05-0203). These commenters stated that they believed that PRA update frequency should also be addressed in guidance rather than regulations. These commenters indicated a frequency of once every two operating cycles would be reasonable and consistent with existing requirements in 10 CFR 50.69(e).

Additionally, some commenters stated the plant-specific PRA used to support a COL application that references a design certification would essentially be the design certification PRA. These commenters expressed the belief that the plant-specific PRA would be updated to be consistent with the PRA scope and quality standards 6 months before the COL was issued as plant-specific design and as-built information was developed during construction. Some commenters argued that this would allow (1) an updated plant-specific PRA that was representative of the as-built plant to be completed, and (2) an updated plant-specific PRA that would be available prior to fuel load for NRC audit and to support plant operations. These commenters suggested that the update of the plant-specific PRA during construction was a matter suitable for guidance.

Some commenters expressed confusion over the NRC proposal to require PRA updates to reflect safety analyses and evaluations performed by the licensee, and analyses of new

safety issues performed by or on behalf of the licensee at the NRC's request. These commenters stated that new analyses and evaluations were often performed using design-basis assumptions that may not be appropriate for a PRA. These commenters suggested that only new analyses that impact the PRA warrant consideration, and requested guidance and examples be developed regarding the information that should be considered when updating the plant-specific PRA.

NRC Response: The NRC staff agrees with the basic intent of the industry comment regarding NRC Question 10, "New Requirements for Periodic Updates to the PRA," which is that the rule does not need to explicitly require combined license holders to submit to the NRC changes to the PRA on a periodic basis. The basis for the requirement for combined license applicants to submit PRA information is that it is needed to aid the NRC staff in confirming that PRA results and risk insights have been used in the design of the facility and in planning for its operation, consistent with the objectives in the Commission's Severe Reactor Accident Policy Statement and Safety Goals Policy Statement. This information helps form the basis for the staff's licensing decision and, once the combined license is issued, there is not a continuing need for the NRC to review updates to the PRA information. The NRC's draft guidance for COL applications does state, however, that the COL applicant should describe their PRA maintenance and update program in Chapter 19 of their FSAR, but does not require the resubmittal of the PRA information. It is expected that the licensee will maintain these PRA models to reasonably reflect the as-built, as-operated plant. In addition, the licensee will be required, in accordance with §§ 50.59 and 50.71, to maintain the FSAR (including Chapter 19) and submit period updates to the NRC. Finally, the NRC will review updated PRA information when it is used as the basis for future amendments to the license or as the basis for participation in other risk-informed regulatory programs. For these reasons, the NRC agrees

with the commenters that the proposed new requirement, identified in NRC Question 10 in this document, is not necessary at this time.

Question 11: In a letter dated July 5, 2005, the Nuclear Energy Institute (NEI) submitted comments on the proposed rule for the AP1000 design certification. Many of those comments have generic applicability to the three pre-existing design certification rules (DCRs) in appendices A–C of 10 CFR part 52. In the final AP1000 rulemaking (January 27, 2006; 71 FR 4464), the Commission adopted some of the NEI-recommended changes, while rejecting others (71 FR at 4465-4468). For those changes that were adopted in the final AP1000 design certification, the Commission indicated that it would consider making the same changes to the existing design certifications in appendices A–C. For those changes that were not adopted in the final AP1000 design certification, the Commission stated that it would reconsider the issues in the part 52 rulemaking, and if the Commission changes its position and the change is adopted, the Commission would make the change for all four design certifications, including the AP1000.

The Commission is considering amending the appropriate sections in each DCR based on the comments below. The Commission considers most of NEI’s proposed changes to be consistent with proposed § 52.63(a)(1); in particular, the Commission believes that the proposed changes would satisfy the “reduces unnecessary regulatory burden” criterion in proposed § 52.63(a)(1)(iii). The few remaining changes, constituting editorial clarifications or corrections reflecting the Commission’s original intent, are not subject to the existing change restrictions in § 52.63(a)(1). Accordingly, the Commission believes that it has authority to incorporate some or all of the NEI-proposed changes into appendices A–D in the final part 52 rulemaking.

The Commission also requests comments on whether some of NEI’s proposed changes accepted in the AP1000 design certification and proposed for inclusion in appendices A–C

should not be included in those appendices in the final part 52 rulemaking because they are unnecessary, or because they would not meet one or more of the change criteria in proposed § 52.63(a)(1). The Commission is also assessing whether NEI's proposed changes which were not adopted in the AP1000 final rulemaking should be adopted in the final part 52 rulemaking for all four design certifications, including the AP1000. The Commission is particularly interested in whether there are reasons, other than those presented by NEI, for adopting those changes, as well as commenter's views on the Commission's reasons for rejecting the NEI proposals as stated in the final AP1000 design certification rulemaking.

a. NEI recommended modification of the generic technical specification definition in Section II.B to clarify that bracketed information is not part the DCRs for purposes of the change processes in Section VIII.C, and an exemption is not required for plant-specific departures from bracketed information. The Commission stated in the section-by-section analysis for the AP1000 DCR (71 FR 4464) that some generic technical specifications and investment protection short-term availability controls contain values in brackets. The values in brackets are neither part of the DCR nor are they binding. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic technical specifications or investment protection short-term availability controls. The Commission believes that including this guidance in each DCR is not necessary. The Commission requests comment on whether there are countervailing considerations that favor inclusion of this provision in the DCRs.

b. NEI recommended modification of the Tier 2 definition in Section II.E to clarify that bracketed information in the investment protection short-term availability controls is not part of Tier 2 and thus not subject to the Section VIII.B change controls. The Commission stated in the section-by-section analysis for the AP1000 DCR (71 FR 4464) that some generic technical specifications and investment protection short-term availability controls contain values in

brackets. The values in brackets are neither part of the DCR nor are they binding. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic technical specifications or investment protection short-term availability controls. The Commission believes that including this guidance in each DCR is not necessary. The Commission requests comment on whether there are countervailing considerations that favor inclusion of this provision in the DCRs.

c. NEI recommended modification of the requirement in Section VIII.C.2 to delete the phrase “or licensee” because that phrase conflicted with the requirement in Section VIII.C.6. The Commission believes that generic technical specifications should not apply to holders of a combined license because the license will include plant-specific technical specifications. Therefore, the Commission is considering amending each of the DCRs to delete the phrase “or licensee” from Section VIII.C.2 and requests public comment on this approach.

d. NEI recommended modification of the requirement in Section VIII.C.6 to delete the last portion, which states “changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.” NEI stated that this sentence is not necessary because it is redundant with § 50.90. It is not necessary to include a provision in each DCR stating that a license amendment is necessary to make changes to technical specifications in order to render this a legally-binding requirement inasmuch as Section 182.a of the AEA requires that technical specifications be part of each license. The Commission believes that clarity and understanding by the reader is enhanced by repeating the statutory requirement in each DCR. The Commission requests comment on whether there are countervailing considerations that favor non-inclusion of this provision in the DCRs, and may decide to remove this provision in the final part 52 rulemaking.

e. NEI recommended modification of the requirement in Section X.A.1 to require the design certification applicant to include all generic changes to the generic technical

specifications and other operational requirements in the generic DCD. The Commission believes that inclusion of changes to the generic technical specifications and other operational requirements will enhance the generic DCD and facilitate its use by referencing applicants. The Commission is considering amending each of the DCRs to include the generic technical specifications and other operational requirements in the generic DCD and requests public comment on this approach.

f. NEI recommended modification of the requirement in Sections IV.A.2 and IV.A.3 to be consistent with respect to inclusion of information in the plant-specific DCD, or explain the difference between “include” (IV.A.2) and “physically include” (IV.A.3). The Commission is considering amending each of the DCRs to use the same term in both provisions, and requests public comment on this approach.

g. NEI recommended modification of the definition in Section II.E.1 to exclude the design-specific probabilistic risk assessment (PRA) and the evaluation of the severe accident mitigation design alternatives (SAMDA) from Tier 2 information. The Commission believes that the PRA and SAMDA evaluations do not need to be included in Tier 2 information because they are not part of the design basis information. The Commission is considering amending each of the DCRs to modify the definition of Tier 2, and requests public comment on this approach.

h. NEI recommended modification of the requirement in Section III.E to use “site characteristics” consistently, instead of “site-specific design parameters.” The Commission intends to use the term “characteristics” to refer to actual values and “parameters” to refer to postulated values. The Commission has proposed amending Section III.E of each DCR to use “site characteristics,” and requests public comment on this approach.

i. NEI recommended modification of Section IV.A.2 to clarify the use of “same information” and “generic DCD” in that requirement. The Commission has proposed amending

Section IV.A.2 of each DCR to use the phrase “same type of information” to avoid confusion, and requests public comment on this approach.

j. NEI recommended modification of the requirement in Section VIII.B.6.a to delete the sentence “The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(4),” in order to be consistent with the requirement in Section VI.B.5 of the DCRs. The Commission believes that departures from Tier 2* information should not receive finality or be treated as resolved issues within the meaning of section VI.B of the DCRs. The Commission requests comment on whether departures from Tier 2* information should be considered a resolved issue, and may decide to remove this provision from each DCR.

k. NEI recommended modification of Section VIII.C.3 to require the NRC to meet the backfit requirements of 10 CFR 50.109 in addition to the special circumstances in 10 CFR 2.758(b) in order to require plant-specific departures from operational requirements. The Commission believes that plant-specific departures should not have to meet the backfit requirement for generic changes. The Commission will have to demonstrate that special circumstances, as defined in § 2.335, are present in order to require a plant-specific departure. The Commission requests comment on whether there are countervailing considerations that would favor modification of this provision in the DCRs.

l. NEI recommended modification of the requirement in Section VIII.C.4 to include a requirement that operational requirements that were not completely reviewed and approved by the NRC should not be subject to any Tier 2 change controls, *e.g.*, exemptions. However, NEI previously proposed that requested departures from Chapter 16 by an applicant for a COL require an exemption (62 FR 25808; May 12, 1997). The Commission believes that the requirement for an exemption applies to technical specifications and operational requirements that were completely reviewed and approved in the design certification rulemaking (see 62 FR

25825). The Commission requests comment on whether departures from technical specifications and operational requirements that were not completely reviewed and approved should also require an exemption.

m. NEI recommended modification of the requirement in Section VIII.C.4 to delete the sentence “The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing,” in order to be consistent with the requirement in Section VI.B.5 of the DCRs. The Commission believes that exemptions from operational requirements should not receive finality or be treated as resolved issues (refer to Section VI.C of the DCRs). The Commission requests comment on whether exemptions from operational requirements should be considered a resolved issue, and may decide to modify this provision in each DCR.

n. NEI recommended modification of the requirement in Section IX.B.1 to better distinguish between NRC staff ITAAC conclusions under proposed Section 52.99(e) and the Commission’s ITAAC finding under proposed Section 52.103(g). The Commission believes that individual DCRs should not address the scope of the NRC staff’s activities with respect to ITAAC verification. This is a generic matter that, if it is to be addressed in a rulemaking, is more appropriate for inclusion in subpart C of part 52 dealing with combined licenses. The Commission requests comment on whether there are countervailing considerations that favor clarification of this provision in the DCRs.

o. NEI recommended modification of the language in Section IX.B.3 to make editorial changes for clarity, *e.g.*, “ITAAC will expire” vs. “their expiration will occur.” The Commission believes that the original rule language is acceptable. The Commission requests comment on whether there are countervailing considerations that favor clarification of this provision in the DCRs.

p. NEI recommended modification of the language in Sections X.B.1 and X.B.3 to clarify references to the design control documents, e.g., “plant-specific” vs. “generic.” The Commission agrees that the references to plant-specific and generic DCD should be clarified in Sections X.B.1 and X.B.3 to ensure that the requirements in these sections are properly implemented by applicants referencing the design certification rules. The Commission requests public comment on this prospective modification.

Commenters’ Response: Several commenters recommended the NRC incorporate the NEI recommendations on the AP1000 rule, cited specific NEI recommendations (71 FR 12834-12836), and made additional suggestions and clarifications.

Regarding NEI recommendations (a) and (b), several commenters suggested it would be sufficient if the statements of considerations for the final rule provided the requested clarification, rather than the rule itself.

Regarding NEI recommendation (f), several commenters supported the use of the term “include” rather than “physically include” for requirements in Section IV of the design certification rules concerning content of COLAs. These commenters also requested clarification on the permissible method of incorporating the generic DCD into the plant-specific DCD portion of the COL application’s final safety analysis report (FSAR), because the current NRC position has apparently “led to considerable confusion” among COL preparers. These commenters noted that in the statements of consideration accompanying the AP1000 final rule, NEI recommended a change to the Definitions (Section III.B of that rule, 71 FR 4466). These commenters stated the NRC staff disagreed with this recommendation, saying that “the generic DCD should also be part of the FSAR, not just incorporated by reference, in order to facilitate the NRC staff’s review of any departures or exemptions.” Some commenters believed that this NRC position was in conflict with the former § 52.79(b), which states that the COL application’s FSAR “may incorporate by reference the final safety analysis report for a certified standard

design,” and with § 50.32, which provides for incorporation by reference to eliminate repetitive information. Some commenters argued that although the wording had been altered, the ability to incorporate by reference was preserved in proposed §§ 52.79 (b) and (c), respectively. These commenters claimed this interpretation of incorporation was validated by NRC staff during the Draft Regulatory Guide (DG)-1145 workshops. These commenters stated support for this interpretation and requested the NRC explicitly describe that either approach is acceptable.

In discussing NEI recommendation (j), several commenters mentioned Section VIII.B.6.a of the design certification rules, which states that an applicant who references the design certification rule must obtain NRC approval for departures from Tier 2* information in the generic DCD. Some commenters believed that this section states the departure is not considered to be a resolved issue under Section VI of the design certification rules. Some commenters indicated this was inconsistent with Section VI.B.5 of the design certification rules, which states that license amendments are considered to be resolved. These commenters expressed support for the revision of Section VIII.B.6. of the design certification rules to make it consistent with Section VIII.B.5 of the design certification rules. These commenters stated that departures from Tier 2* information that are reviewed and approved by the NRC in the combined license proceeding should have finality for the plant in question.

With respect to NEI recommendation (k), several commenters expressed concern that Section VIII.C.3 of the design certification rules “inappropriately” allowed the NRC to make changes to operational requirements in the DCD without satisfying the backfit requirements in § 50.109. These commenters stated that the operational requirements in the design certification proceeding should be afforded the protection of the backfit rule. Some commenters supported a revision to Section VIII.C.3 of the design certification rules to include a reference to § 50.109 for these changes.

In the discussion of NEI recommendations (l) and (m), several commenters mentioned Section VIII.C.4 of the design certification rules, which states a COL applicant must request an exemption from the NRC if the applicant wants to depart from the generic technical specifications or other operational requirements. These commenters described this requirement as “unduly burdensome.” These commenters noted that the operational requirements do not have finality under Section VI.C of the design certification rules, and that no basis existed for applying such a change control process to a COL applicant seeking to change operational requirements. Some commenters cited Section VIII.B.5 of the design certification rules, which states a COL applicant may depart from final design-related provisions in the design certification rule using a “§ 50.59-like” process, and argued that imposing an exemption process with respect to operational provisions was not required. Some commenters recommended Section VII.C.4 be amended to state that a departure from an operational requirement does not require an exemption.

Several commenters mentioned information from NEI’s September 30, 2003, response to the 2003 part 52 notice of proposed rulemaking. These commenters expressed support for the need to add a basic definition of “departure” to the DCRs to be consistent with adding the definition of “departure from a method of evaluation,” and stated that both should be based on Regulatory Guide 1.187. The commenters stated, “The basic definition of ‘change or departure’ should precede the definition of departure from a method of evaluation.” Some commenters recommend adding the new definition as paragraph II.G and renaming the final two paragraphs as II.H and II.I.

NRC Response: In response to question 11.a, the NRC has decided that modification of the generic technical specification definition in Section II.B of the design certification rules (DCRs) is not necessary. As stated in the section-by-section analysis for the AP1000 DCR (71 FR at 4475):

Some generic technical specifications and investment protection short-term availability controls contain values in brackets []. The brackets are placeholders indicating that the NRC's review is not complete, and represent a requirement that the applicant for a combined license referencing the AP1000 DCR must replace the values in brackets with final plant-specific values. The values in brackets are neither part of the design certification rule nor are they binding. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic technical specifications or investment protection short-term availability controls.

The NRC believes that the above guidance resolves NEI's concern regarding bracketed information in the generic technical specifications.

Regarding question 11.b, the NRC has decided that modification of the Tier 2 definition in Section II.E of the DCRs is not necessary. The NRC believes that the previously mentioned guidance resolves NEI's concern regarding bracketed information in the investment protection short-term availability controls located in the Tier 2 information.

Regarding question 11.c, the NRC agrees with NEI's recommendation and has decided to delete the phrase "or licensee" from Section VIII.C.2 of the DCRs because the generic technical specifications will not apply to holders of a combined license.

Regarding question 11.d, the NRC has decided not to modify the rule language in Section VIII.C.6 of the DCRs, which state that "changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90." The Commission believes that this statement provides clarity to this requirement.

Regarding question 11.e, the NRC agrees with NEI's recommendation and has decided to modify the requirement in Section X.A.1 of the DCRs. The Commission believes that the inclusion of changes to the generic technical specifications and other operational requirements

in the generic design control document (DCD) will enhance the DCD and facilitate its use by referencing applicants.

Regarding question 11.f, the NRC has decided to modify Section IV of the DCRs to consistently use the term “include” rather than “physically include” as recommended by NEI.

Several commenters also requested clarification on the permissible method of incorporating the generic DCD in the plant-specific DCD portion of the COL application’s final safety analysis report (FSAR), because the NRC position has apparently “led to considerable confusion” among COL preparers. The NRC is requiring COL applicants that reference the DCRs in appendices A through D of part 52 to include the generic DCD in the application’s FSAR, in order to facilitate the NRC staff’s review of any departures or exemptions. Simply incorporating the generic DCD by reference into the FSAR is not sufficient because of the manner in which these existing DCDs were submitted to the NRC. Therefore, Section IV.A.2 of the DCRs overrides §§ 50.32 and 52.79(d). The NRC is hopeful that future DCRs will not have to use this special requirement.

Regarding question 11.g, the NRC agrees with NEI’s recommendation and has decided to modify the definition of Tier 2 in Section II.E.1 of the DCRs to exclude the design-specific probabilistic risk assessment (PRA) and the evaluation of the severe accident mitigation design alternatives (SAMDA). The NRC believes that the PRA and SAMDA evaluations do not need to be included in Tier 2 because they are not part of the design basis information. Also, the revised Section II.E.1 is now consistent with the requirements in the new § 52.80 regarding PRA and SAMDA evaluations.

Regarding question 11.h, the NRC agrees with NEI’s recommendation to use “site characteristics” instead of “site-specific design parameters” in Section III.E of the DCRs. This modification of the rule language in Section III.E was made in the proposed rule and, therefore, no change was made to the final rule.

Regarding question 11.i, the NRC agrees with NEI's recommendation to clarify the rule language in Section IV.A.2.a of the DCRs and adopts the phrase "same type of information" to avoid confusion. An applicant for a combined license must submit, as part of its application, a plant-specific DCD that contains the same type of information and uses the same organization and numbering as the generic DCD. This organization will facilitate the NRC staff's review of the plant-specific DCD. The NRC recognizes that the plant-specific DCD will not contain the exact, same information as the generic DCD because the plant-specific DCD will be modified and supplemented by the applicant's exemptions, departures, and COL action items.

Regarding question 11.j, the NRC does not agree with NEI's request to modify the requirement in Section VIII.B.6.a of the DCRs. The Commission decided during the initial design certification rulemakings that departures from Tier 2* information (by an applicant) would not receive finality or be treated as a resolved issue within the meaning of Section VI of the DCR. This provision applies to applicants for a combined license and the new information is subject to litigation in the same manner as other plant-specific issues in the licensing hearing. Also, Tier 2* information has the same safety significance as Tier 1 information and would have received the Tier 1 designation, except that NRC decided to provide more flexibility for this type of information.

Regarding question 11.k, the NRC does not agree with NEI's recommendation to modify Section VIII.C.3 of the DCRs. NEI requests that the NRC meet the backfit requirements in § 50.109 in addition to the special circumstances in § 2.335 in order to require plant-specific departures from operational requirements. In the original design certification rulemakings, the Commission decided on different standards for changes made under Section VIII.C (see Section VI.C and 62 FR at 25805; May 12, 1997). The Commission has decided that plant-specific departures should not have to meet the backfit requirements in § 50.109.

Regarding question 11.l, the NRC does not agree with NEI's recommendation to modify Section VIII.C.4 of the DCRs. The requirement in Section VIII.C.4 for an applicant to request an exemption applies to generic technical specifications and operational requirements that were comprehensively reviewed and finalized in the design certification rulemaking (see 62 FR at 25825; May 12, 1997). If not, there is no restriction on plant-specific changes to the technical specifications or operational requirements, and exemptions are not required. Because this guidance is already set forth in the section-by-section discussion for the DCRs, the NRC has decided that changes to the rule language are not necessary.

Regarding question 11.m, the NRC does not agree with NEI's recommendation to delete the last sentence from Section VIII.C.4 of the DCRs. This sentence applies to applicants for a combined license and the new information is subject to litigation in the same manner as other plant-specific issues in the licensing hearing. The Commission believes that exemptions from operational requirements should not receive finality or be treated as resolved issues (refer to Section VI.C of the DCRs).

Regarding question 11.n, the NRC does not agree with NEI's recommendation to modify Section IX.B.1 of the DCRs. The NRC has decided that individual DCRs should not address the scope of the NRC staff's activities with respect to ITAAC verification. This is a generic matter that was addressed in § 52.99(e).

Regarding question 11.o, the NRC does not agree with NEI's request to clarify the phrase "their expiration will occur" in Section IX.B.3 of the DCRs. The NRC has decided that the original rule language is acceptable.

Regarding question 11.p, the NRC agrees with NEI's recommendation to clarify references to the DCDs in Sections X.B.1 and X.B.3 of the DCRs. The references to plant-specific and generic DCD were revised in Sections X.B.1 and X.B.3 to ensure that the

requirements in these sections will be properly implemented by applicants and licensees that reference the design certification rules.

Question 12: The Commission is considering adopting in the final part 52 rulemaking a new provision that would either require combined license applicants to submit a detailed schedule for the licensee's completion of ITAAC or require the combined license holder to submit the schedule for ITAAC completion. Delaying submission of the schedule would allow the combined license holder to develop the schedules based on more accurate information regarding construction schedules and would allow the schedule to be submitted at a time when it would be most useful to the NRC for planning purposes. The Commission could require that applicants submit the schedule within a specified time prior to scheduled COL issuance, for example, 3 months prior to COL issuance, or within some time period (e.g., 6 months or 1 year) after COL issuance. In addition, the Commission is considering an additional element to this provision that would require that the licensee submit an update to the ITAAC schedule within 12 months after combined license issuance and that the licensee update the schedule every 6 months until 12 months before scheduled fuel load, and monthly thereafter until all ITAAC are complete. The Commission is considering adopting these requirements to support the NRC staff's inspection and oversight with respect to ITAAC completion, and to facilitate publication of the *Federal Register* notices of successful completion of ITAAC as required by proposed § 52.99(e). The Commission requests stakeholder comment on whether such a provision, with or without the update element, should be added to the Commission's regulations and which time frame for submission of the schedule would be most beneficial.

The Commission is also considering adopting a provision that would establish a specific time by which the licensee must complete all ITAAC to allow sufficient time for the NRC staff to verify successful completion of ITAAC, without adversely affecting the licensee's scheduled date for fuel load and operation. The Commission considers "60 days prior to the schedule

date for initial loading of fuel” to be a reasonable time period by which all ITAAC must be completed. However, the Commission requests comments on whether this time period would provide too much or too little time prior to scheduled fuel load. Alternatively, the Commission is considering a 30-day or a 90-day time period prior to scheduled fuel load. The 30-day option would allow more flexibility for the licensee to complete ITAAC late in construction but would require immediate action on the part of the NRC (to determine if the final ITAAC were completed successfully and, if so, for the Commission to make its finding under § 52.103(g)) so as not to delay scheduled fuel load. The 90-day option would reduce licensee flexibility to complete ITAAC late in construction but would ensure that the NRC had ample time to make its determination on the final ITAAC for Commission review of all ITAAC under § 52.103(g). The Commission requests stakeholder comment on whether a provision requiring completion of ITAAC within a certain time period prior to scheduled fuel load should be added to the Commission’s regulations.

Commenters’ Response: Several commenters believed it was unnecessary to include a requirement for either the COL applicant or the COL holder to submit a detailed schedule for ITAAC completion because a COL applicant could provide only a progressively less accurate estimated completion schedule. Some commenters stated that the COL holder would have schedules at the site, and those schedules would be available for NRC review. Some commenters believed that COL holders would interact and coordinate with the NRC to ensure that NRC had sufficient information to schedule its inspection activities for ITAAC, making a regulatory requirement for submission of a schedule unnecessary. In addition, these commenters noted that a COL applicant/holder would likely consider detailed schedule information to be proprietary information, which would make its submission inappropriate.

Several commenters also stated it was “wrong” to require completion of ITAAC in a set time period prior to fuel loading and operation. These commenters indicated that a COL holder

would likely complete several ITAAC within 30 days of fuel loading and argued that the NRC should not abrogate responsibility by imposing a mandatory delay on licensees. Some commenters stated the importance of the NRC providing the appropriate level of inspections and reviews to prevent delays in fuel load and emphasized the high cost (stated to be on the order of \$1,000,000 per day) of such delay. Some commenters suggested the NRC should be in a position to make a § 52.103(g) finding promptly following the completion of the last ITAAC.

NRC Response: The NRC has decided to amend § 52.99 to require licensees to submit their detailed schedules for completing the inspections, tests, or analyses in the ITAAC. The NRC has added a new paragraph (a) in § 52.99 that requires licensees to submit to the NRC, no later than 1 year after issuance of the combined license, detailed schedules for completing the inspections, tests, or analyses in the ITAAC. Licensees are required to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, licensees must submit updates to the ITAAC schedule every 30 days until the final ITAAC is completed or until the final notification is provided to the NRC under § 52.99(c). Although commenters did not believe that a requirement for submission of a schedule was necessary, the NRC believes it is necessary to ensure that the NRC has sufficient information to plan all of the activities necessary for the NRC to support the Commission's determination as to whether all of the ITAAC have been met prior to initial operation. In the event that licensees consider their schedule information to be proprietary, they can request that the schedule be withheld from public disclosure under § 2.390.

The NRC has also decided to amend § 52.99(c) which requires the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met. The NRC is revising § 52.99(c) in the final rule to clarify that the notification must contain sufficient information to demonstrate that the inspections, tests, or analyses have been successfully completed and that the acceptance

criteria have been met. The NRC is adding this clarification to ensure that combined license applicants and holders are aware that the NRC expects the notification of ITAAC completion to contain more information than just a simple statement that the licensee believes the ITAAC has been completed and the acceptance criteria met. The NRC expects the notification to be sufficiently complete and detailed for a reasonable person to understand the bases for the licensee's representation that the inspections, tests and analyses have been successfully completed and the acceptance criteria have been met. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes "sufficient information" for such a demonstration.

The NRC is also revising § 52.99(c) by adding a new paragraph (c)(2) requiring that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by § 52.99(c)(1) for all ITAAC, then the licensee must notify the NRC that the inspections, tests, or analyses for all uncompleted ITAAC will be successfully completed and all acceptance criteria will be met prior to initial operation (consistent with the Section 185.b requirement that the Commission, "prior to operation," find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the inspections, tests, or analyses will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met. Paragraph (e) has been revised to require that the NRC make available to the public the notifications to be submitted under § 52.99(c)(1) and (c)(2), no later than the *Federal Register* notice of intended operation and opportunity for hearing on ITAAC under § 52.103(a). A conforming change is included in § 2.105(b)(3) to require that the § 52.103(a) notice

reference the public availability of the § 52.99(c)(1) and (2) notifications. The NRC is requiring that the paragraph (c)(2) notification be made 225 days before the date scheduled for initial loading of fuel, in order to ensure that the licensee notifications are publicly available through the NRC document room and online through the NRC Web site at the same time that the § 52.103(a) notice is published in the *Federal Register*. The NRC's goal is to publish that notice 210 days before the date scheduled for fuel loading, but in all cases the § 52.103(a) notice would be published no later than 180 days before the scheduled fuel load, as required by Section 189.a(1)(B).

Commenters did not support addition of a requirement on completion of ITAAC in a set time period prior to fuel load and the NRC has not included a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date. Instead, the NRC has decided to modify the concept slightly by requiring the licensee to submit, with respect to ITAAC which have not yet been completed 225 days before the scheduled date for initial loading of fuel, additional information addressing whether those inspections, tests and analyses will be successfully completed and the acceptance criteria met before initial operation. In the case where the licensee has not completed all ITAAC by 225 days prior to its scheduled fuel load date, the NRC expects the information that the licensee submits related to uncompleted ITAAC to be sufficiently detailed such that the NRC can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. In addition, the NRC is adopting the requirements in paragraphs (c)(1) and (c)(2) to ensure that interested persons will be able to meet the Atomic Energy Act, Section 189.a(1), threshold for requesting a hearing with respect to both completed and as-yet uncompleted ITAAC. The NRC therefore expects that the information submitted by licensees in the § 52.99(c)(2) notification will be sufficiently complete and detailed such that any

licensee response to a contention on both completed and uncompleted ITAAC would ordinarily be answered solely by reference to information contained in the notification. Furthermore, the NRC expects that any contentions submitted by prospective intervenors regarding uncompleted ITAAC would focus on the inadequacies of the procedures and analytical methods described by the licensee for completing those ITAAC in the context of the reasonable assurance finding under § 52.103(b)(2). Therefore, the level of detail provided by the licensee should be sufficient to allow a prospective intervenor to form such judgments by reference to that information. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes “sufficient information” to demonstrate that the inspections, tests, or analyses for uncompleted ITAAC will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met.

The NRC notes that, even though it did not include a provision requiring the completion of all ITAAC by a certain time prior to the licensee’s scheduled fuel load date, the NRC will require some period of time to perform its review of the last ITAAC once the licensee submits its notification that the ITAAC has been successfully completed and the acceptance criteria met. In addition, the Commission itself will require some period of time to perform its review of the staff’s conclusions regarding all of the ITAAC and the staff’s recommendations regarding the Commission finding under § 52.103(g). Therefore, licensees should structure their construction schedules to take into account these time periods. The NRC staff intends to develop regulatory guidance on the licensee’s completion and NRC verification of ITAAC and will provide estimates of the time it expects to take to verify successful completion of various types of ITAAC. The NRC expects that such guidance, along with frequent communication with licensees during construction, will provide licensees with adequate information to plan initial fuel loading and related activities.

Question 13: ML Hearings. As discussed in Section IV.F.6 of the March 13, 2006, proposed rule, the Commission proposes, as a matter of policy and discretion, that the Commission hold a “mandatory” hearing (*i.e.*, a hearing which, under NRC requirements in 10 CFR part 2, is held regardless of whether the NRC receives any hearing requests or petitions to intervene) in connection with the initial issuance of every manufacturing license. The Commission believes that Section 189.a.(1)(A) of the AEA does not require that a hearing be held in connection with the initial issuance of a manufacturing license. Nonetheless, there are several reasons for the Commission to require by rule, as a matter of discretion, a mandatory hearing. A manufacturing license may be viewed as analogous to a construction permit—a regulatory approval for which Section 189 of the AEA specifically requires that a hearing be held. Even though the Commission’s regulations did not address the hearing requirements for manufacturing licenses, the Commission noticed a “mandatory” hearing in connection with the only manufacturing license application ever received by the Agency. *Offshore Power Systems (Floating Nuclear Power Plants)*, 38 FR 34008 (December 10, 1973). Accordingly, proposed §§ 2.104 and 52.163 require that a mandatory hearing be held in each proceeding for initial issuance of a manufacturing license. However, the Commission recognizes that there may be countervailing considerations weighing against Commission adoption of a rulemaking provision mandating that a hearing be held in connection with the initial issuance of every manufacturing license where there has been no stakeholder interest in a hearing. If there is no stakeholder interest in a hearing, transparency and public confidence would not appear to be relevant considerations in favor of holding a mandatory hearing. Considerations of regulatory efficiency and effectiveness would be paramount, and would weigh against holding of a mandatory hearing. The Commission requests comments on whether the Commission should exercise its discretion to provide by rule an opportunity for hearing, rather than a mandatory hearing, and the reasons in favor of providing an opportunity for hearing as

opposed to holding a mandatory hearing. Based upon the public comments, the Commission may adopt a final rule which deletes § 2.104(f), revises § 2.105 (governing the content of a *Federal Register* notice of proposed action where a mandatory hearing is not held under § 2.104) to add, as appropriate, references to issuance of manufacturing licenses, and revised § 52.163 to provide an opportunity for hearing rather than a mandatory hearing in connection with the initial issuance of a manufacturing license.

Commenters' Response: Several commenters stated there was no need to require mandatory hearings for manufacturing licenses, or that the need for such hearings was unclear. These commenters expressed the belief that such hearings were not an appropriate method for reviewing and resolving technical issues. Some commenters advised that the decision to request a hearing be left to either the NRC staff or stakeholders.

NRC Response: As stated in the statement of considerations for the March 13, 2006, proposed rule, the NRC acknowledges that hearings on initial issuances of manufacturing licenses are not required by the AEA (71 FR at 12814). The NRC also agrees with the general premise of the commenters that adjudicatory hearings may not be the best approach for resolving technical design issues - especially in uncontested proceedings. Indeed, the NRC removed the opportunity for adjudicatory-style hearings for design certifications as part of the 2004 changes to 10 CFR part 2 (January 14, 2004; 69 FR 2182). The primary responsibility for determining the safety of an application is with the NRC staff, and not the presiding officer. This is true regardless of whether the proceeding is contested or uncontested. Public confidence would not seem to be enhanced in any significant manner by the holding of a hearing where there is no request that the NRC hold a hearing. Accordingly, the NRC has decided not to adopt in the final Part 52 rule a requirement for a "mandatory" hearing in connection with issuance of manufacturing licenses.

Question 14: As discussed in Section IV.C.5.g of the statements of consideration of the March 13, 2006, proposed rule, the proposed rule would amend the special backfit requirement in 10 CFR 52.63(a)(1) to provide the Commission with the ability to make changes to the design certification rules (DCRs) or the certification information in the generic design control documents that reduce unnecessary regulatory burdens. The underlying rationale for this provision also forms the basis for amending the Tier 2 change process in the three DCRs (appendices A, B, and C of part 52) to incorporate the revised change criteria in 10 CFR 50.59.

The Commission is considering adopting an additional provision [§ 52.63(a)(1)(iv)] in the final rule that would allow amendments of design certification rules to incorporate generic resolutions of design acceptance criteria (DAC) or other design information without meeting the special backfit requirement in the current § 52.63(a)(1). The applicants for the current DCRs requested use of DAC in lieu of providing detailed design information for certain areas of their nuclear plant designs, for example, instrumentation and control systems. Under the proposed requirements, a generic change to design certification information would have to meet the special backfit requirement of § 52.63(a)(1) or reduce an unnecessary regulatory burden while maintaining protection to public health and safety and the common defense and security. The Commission adopted this special backfit requirement to restrict changes and to require that everyone meet the same backfit standard for generic changes, thereby ensuring that all plants built under a referenced DCR would be standardized. By allowing a DCR amendment to include generic resolutions of DAC or other design information, the Commission would enhance its goals for design certification, for example, early resolution of all design issues and finality for those issue resolutions, which would avoid repetitive consideration of design issues in individual combined license proceedings.

There are currently three ways of resolving generic design issues: (1) the combined license applicant that references a DCR could submit plant-specific resolutions in its

application, which could result in loss of standardization; (2) a vendor could submit generic resolutions in topical reports that, if approved, could but would not be required to be referenced in a combined license application; or (3) the Commission could exempt itself from the special backfit requirement in § 52.63(a)(1) and amend the DCR to incorporate a generic resolution, which could result in multiple rulemakings to revise each DCR to incorporate each generic resolution. The Commission intends that any review of a proposed generic resolution would be performed under the regulations that are applicable and in effect at the time that the approval or amendment is completed.

Therefore, the NRC is requesting public comments on: (1) whether a provision should be added to § 52.63(a)(1) to allow generic amendments to design certification information that meet applicable regulations in effect at the time that the rulemaking is completed; and (2) whether the generic resolutions should be incorporated into a DCR without meeting a backfit requirement, which would provide for completion of the design certification information and facilitate standardization, or whether an application for a generic amendment should be required to meet a backfit requirement (*e.g.*, § 50.109).

Commenters' Response: Some commenters stated that revisions to NRC regulations should include the current 10 CFR 52.63, which they believed should allow the original design certification applicant (or its successor) to obtain amendments to the design certification rule. These commenters believed current regulations prevented any amendment to a design once the design has been certified by rule (10 CFR 52.63(a)(1)). Some commenters stated that the design certification applicant should be able to petition the NRC for, and obtain, an amendment to the design certification rule to incorporate "beneficial" changes to the design certification, including: (1) design changes that would result in significant improvements in safety; (2) design changes that would result in significant improvements in efficiency, reliability and/or economics; (3) design changes that result from continuing engineering or design work or are required

because of lack of availability of components specified in the original design certification; and (4) design changes necessary to correct minor errors in the original design certification. Some commenters also suggested that where proposed changes involved changes to Tier 2, the design certification applicant should be able to make such changes using a § 50.59-like change process. One commenter noted that changes to allow an amendment to the final design certification could potentially simplify COL applications, reduce NRC staff resource burden, and help assure standardization across the industry.

NRC Response: The NRC has decided to include an amendment process for design certifications in the final rule that allows for: (1) generic resolutions of design acceptance criteria; (2) correction of errors; or (3) other changes that increase standardization, without meeting the special backfit requirement in the former § 52.63(a)(1). These amendments will apply to all plants that have referenced or will reference the DCR. The NRC believes that these amendments will enhance standardization by further completing or correcting the certification information. A detailed discussion of the comments on this amendment process is provided in Section V.C.7.g of the supplementary information.

Question 15: In Section IV.J of the Supplementary Information of the March 13, 2006, proposed rule, the NRC outlines key principles regarding its proposal for reporting requirements that implement Section 206 of the Energy Reorganization Act, as amended, for part 52 licenses, certifications, and approvals. The NRC discusses that the beginning of the “regulatory life” of a referenced license, standard design approval, or standard design certification under part 52 occurs when an application for a license, design approval, or design certification is docketed. The NRC also cautions, however, that this does not mean that an *applicant* is without Section 206 responsibilities for pre-application activities because there are two aspects to the reporting requirements, namely, a “backward looking” or retrospective aspect with respect to existing information, and a “forward looking” or prospective aspect with respect to

future information. For an early site permit applicant, the retrospective obligation is that the early site permit holder and its contractors, upon issuance of the early site permit, must report all known defects or failures to comply in “basic components,” as defined in part 21. Under the proposed part 21 requirements presented in the proposed rule, the early site permit holder and its contractors are required to meet these requirements upon issuance of the early site permit. Accordingly, applicants should procure and control safety-related design and analysis or consulting services in a manner sufficient to allow the early site permit holder and its contractors to comply with the above described reporting requirements of Section 206, as implemented by part 21. A similar argument applies to design certification applicants. Although the Commission has not proposed an explicit requirement imposing part 21 on *applicants* for an early site permit or design certification in the proposed rule, it is considering adopting such a requirement in the final part 52 rulemaking because, as a practical matter, the NRC has to require these applicants to implement a part 21 program before approval of the early site permit or design certification. Therefore, providing explicit part 21 requirements for applicants would clarify the Commission’s intent. The Commission requests stakeholder comment on whether it should, in the final rule, impose part 21 reporting requirements on applicants for early site permits and design certifications.

Commenters’ Response: Several commenters were opposed to the proposed changes to part 21. Some commenters stated part 21 had been in existence for almost 30 years, during which it was never applied to applicants. They complained that they were not aware, and the NRC had not made them aware, of problems that would warrant a change. The commenters noted that applicants take measures to ensure that they were made aware of any errors and deficiencies identified by contractors and suppliers for work performed on commercial nuclear projects, because applicants eventually become holders, and licensees and want equipment to operate correctly. Several commenters were also concerned that the proposal was contrary to

the Energy Reorganization Act (ERA), which was the basis for part 21. They believed it would be inappropriate and contrary to the ERA to apply part 21 to applicants. They stated part 21 was established to implement § 206 of the ERA, which applies to “licensees” and vendors, suppliers, and contractors of licensees, not to “applicants.” These commenters cited 10 CFR 21.2, stating that the existing regulations of part 21 apply only to entities licensed to possess, use, or transfer radioactive material within the United States, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or fuel storage facility. The commenter believed applicants did not fall within the scope of § 206 of the ERA, and it was inconsistent with the Act to expand the scope of § 21.2 to include applicants.

Some commenters also noted that it had been the standard practice for a construction permit (CP) applicant to specify part 21 requirements in its procurement contracts for a plant prior to issuance of the construction permit. Some commenters agreed with this practice because part 21 was applicable to such contracts once the CP was issued by the NRC, and expected that this “good practice” would be implemented by COL applicants as well. From a “practical perspective,” the commenters believed this negated the need to expand part 21 to applicants.

Some commenters argued that the obligations for applicants to provide information to the NRC under proposed § 52.6(a) was broader than the obligation in part 21, and would require applicants to update and correct their applications to account for the types of defects and noncompliances covered by part 21. These commenters stated the industry had no objection to proposed § 52.6(a), which should therefore eliminate the need to apply part 21 to applicants.

NRC Response: The Commission proposed part 21 reporting requirements on applicants for early site permits, design certifications, and standard design approvals in the

proposed rule. A detailed discussion on the Commission's rationale for imposing these requirements in the final rule is provided in Section V.J of the Supplementary Information of this document.

V. Discussion of Substantive Changes and Responses to Significant Comments.

A. Introduction.

The changes to 10 CFR Chapter 1 are further discussed by part. Changes to parts 52 and 50 are discussed first, followed by changes to other parts in numerical order. Within each part, general topics are discussed first, followed by discussion of changes to individual sections as necessary. In addition to the substantive changes, rule language was revised to make conforming administrative changes (*e.g.*, identification of regulations containing information collection requirements in § 52.11), correct typographic errors, adopt consistent terminology (*e.g.*, "makes the finding under § 52.103(g)"), correct grammar, and adopt plain English. These changes are not discussed further.

B. Testing Requirements for Advanced Reactors.

This rule amends §§ 50.43, 52.47, 52.79, and 52.157 to achieve clarity and consistency in the testing requirements for advanced reactor designs and plants. This amendment requires applicants for a combined license, operating license, or manufacturing license that use new safety features but do not reference a certified advanced reactor design to also perform the design qualification testing required of certain applicants for design certification. If a combined

license application references a certified design, the necessary qualification testing will have been performed under § 52.47(c)(2). The codification of testing requirements in the original § 52.47 was a principal issue during the development of 10 CFR part 52 (see Section II of 54 FR 15372; April 18, 1989). The requirement to demonstrate the performance of new safety features for nuclear power plants that differ significantly from evolutionary light-water reactors or that use simplified, inherent, passive, or other innovative means to accomplish their safety functions (advanced reactors), were included in 10 CFR part 52 to ensure that these new safety features will perform as predicted in the applicant's safety analysis report, to provide sufficient data to validate analytical codes, and that the effects of systems interactions are acceptable. The design qualification testing requirements may be met with either separate effects or integral system tests; prototype tests; or a combination of tests, analyses, and operating experience. These requirements implement the Commission's policy on proof-of-performance testing for all advanced reactors and its goal of resolving all safety issues before authorizing construction.

Some commenters stated that it is unnecessary to apply qualification testing requirements to combined license applicants. The Commission does not agree because, when it reformed the licensing process for new nuclear plants with the issuance of part 52, the Commission required applicants to demonstrate that new safety features will perform as predicted in the final safety analysis report. Although the focus of the NRC at that time was on applications for design certification, the Commission intended that testing to qualify new design features (proof-of-performance testing) would be required for all advanced reactors, including custom designs (see Question 6 at 51 FR 24646; July 8, 1986). Furthermore, it would make no sense for the Commission to require qualification testing for design certification applicants (so-called paper designs) and not require testing for applications to build and operate an advanced nuclear power plant. Therefore, the NRC has implemented its intent in adopting part 52 to

resolve issues early and its policy on advanced reactors that it is necessary to demonstrate the performance of new or innovative safety features through design qualification testing for all advanced nuclear reactor designs or plants (including nuclear reactors manufactured under a manufacturing license).

This amendment also includes a requirement in § 50.43(e)(2) for licensing a prototype plant, as defined in §§ 50.2 and 52.1, if the plant is used to meet the testing requirements in § 50.43(e)(1). The new § 50.43(e) states that, if a prototype plant is used to comply with the qualification testing requirements, the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to compensate for any uncertainties associated with the performance of the new or innovative safety features in the prototype plant.

Some commenters stated that it would be inappropriate to establish or impose prototype testing on combined license applicants. Although the Commission stated that it favors the use of prototypical demonstration facilities and that prototype testing is likely to be required for certification of advanced non-light-water designs (see Advanced Reactor Policy Statement at 51 FR 24646; July 8, 1986, and the statement of consideration for 10 CFR part 52, 54 FR 15372; April 18, 1989), this rule does not require the use of a prototype plant for qualification testing. Rather, this rule provides that if a prototype plant is used to qualify an advanced reactor design, then additional conditions may be required for the licensed prototype plant to compensate for any uncertainties with the unproven safety features. Also, the prototype plant could be used for commercial operation.

C. Changes to 10 CFR Part 52.

1. Use of Terms: *Site characteristics*, *Site parameters*, *Design characteristics*, and *Design parameters* in §§ 52.1, 52.17, 52.24, 52.39, 52.47, 52.54, 52.79, 52.93, 52.157, 52.158, 52.167, 52.171, and Appendices A, B, and C to part 52.

The NRC is revising 10 CFR part 52 to clarify the use of the terms, *site characteristics*, *site parameters*, *design characteristics*, and *design parameters*, in order to ensure that the NRC's requirements governing applications for and issuance of early site permits, design approvals, design certifications, combined licenses, and manufacturing licenses are expressed in clear and unambiguous terms. This final rule adds or revises these terms where necessary to reflect this clarification. Corresponding changes are made to §§ 52.17, 52.24, 52.39, 52.47, 52.54, 52.79, 52.93, 52.157, 52.158, 52.167, 52.171, and Section III.E of appendices A, B, and C to part 52.

The NRC is also adding definitions of the terms *design characteristics*, *design parameters*, *site characteristics*, and *site parameters* to § 52.1 to clarify the use of these terms. *Design characteristics* are defined as the actual features of a reactor. Design characteristics are specified in a standard design approval, a standard design certification, a combined license application, or a manufacturing license. *Design parameters* are defined as the postulated features of a reactor or reactors that could be built at a proposed site. Design parameters are specified in an early site permit. *Site characteristics* are defined as the actual physical, environmental and demographic features of a site. Site characteristics are specified in an early site permit or in a final safety analysis report for a combined license. *Site parameters* are defined as the postulated physical, environmental and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or a manufacturing license.

In addition, the NRC is revising § 52.79 to include a requirement that a combined license application referencing a certified design must contain information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit. Former § 52.79 included a requirement that a combined license application referencing an early site permit contain information sufficient to demonstrate that the design of the facility falls within the *parameters* specified in the early site permit. The NRC interprets *parameters* to mean the site characteristics and design parameters as defined in § 52.1. The NRC is making similar changes to §§ 52.39 and 52.93. The need for these changes became evident during NRC's review of the pilot early site permit applications. Because the NRC is relying on certain design parameters specified in the early site permit applications to reach its conclusions on site suitability, these design parameters will be included in any early site permit issued. The NRC believes that these changes, in the aggregate, will provide sufficient clarification on the use of the terms in question.

As the NRC completes its review of the first early site permit applications and prepares for the submittal of the first combined license application, it is focusing on the interaction among the early site permit, design certification, and combined license processes. The NRC believes that its review of a combined license application that references an early site permit will involve a comparison to ensure that the actual characteristics of the design chosen by the combined license applicant fall within the design parameters specified in the early site permit. NRC review of a combined license application that references a design certification will involve a comparison to ensure that the actual characteristics of the site chosen by the combined license applicant fall within the site parameters in the design certification. Similarly, if a combined license applicant references both an early site permit and a design certification, the NRC will review the application to ensure that the site characteristics in the early site permit fall within the site parameters in the referenced design certification and that the actual characteristics of the

certified design fall within the design parameters in the early site permit. For these reasons, the NRC believes it is important to make the changes described above in order to clarify these terms and their use in part 52 licensing processes.

2. Issuance of Combined and Manufacturing Licenses (§§ 52.97 and 52.167).

Current § 50.50 sets forth the NRC's authority to include conditions and limitations in permits and licenses issued by the NRC under part 50. Similar language delineating the NRC's authority in this regard is also set forth in § 52.24 for early site permits, but is not included in part 52 with respect to either combined licenses or manufacturing licenses. There are two possible ways of addressing this omission: § 50.50 could be revised to refer to combined licenses and manufacturing licenses, or provisions analogous to § 50.50 could be added to the appropriate sections in part 52 for combined licenses and manufacturing licenses. Inasmuch as the NRC's inclusion of appropriate conditions in combined licenses is not a technical matter per se but rather a matter of regulatory authority, the most appropriate location for this provision appears to be in part 52. Inclusion of these provisions in appropriate portions of part 52 would be consistent with the provision applicable to early site permits in § 52.24. Accordingly, the NRC is adding the language in § 52.97(c) for combined licenses, and § 52.167(b) for manufacturing licenses, which are analogous to § 50.50.

3. NRC Staff Information Requests.

Section 52.47(a)(3) of the 1989 part 52 rulemaking provided that the NRC staff would advise the design certification applicant on whether there was any additional information

beyond that required to be submitted by that section, that must be submitted. The March 2006 proposed rule included analogous provisions (§§ 52.17(d), 52.79(a)(42), 52.137(a)(27), and 52.157(p)) for each of the other licensing and regulatory approval processes in part 52. Upon further consideration in response to a comment on the March 2006 proposed rule, the Commission has decided that these provisions are redundant to § 2.102(a), which provides the NRC staff with overall authority to request information to support their review of an application. Accordingly, §§ 52.17(d), 52.79(a)(42), 52.137(a)(27), and 52.157(p) of the proposed rule have not been adopted in the final rule, and § 52.47(a)(3) is removed from part 52.

4. Changes to a Design Certification, Departures, Variances, Exemptions.

External stakeholders have expressed confusion over the years in public meetings and in written comments submitted under various circumstances with respect to the meaning of the terms, *change to a design certification*, *departures*, *variances*, and *exemptions*. To clarify the meaning of these terms, the Commission provides the following explanation of these terms.

Change to a design certification

A *change to a design certification* is a generic change to the design certification information which is approved by the Commission in a standard design certification rule under subpart B of part 52. In the four design certifications currently approved by the Commission, the design certification information which is approved by the Commission is either “certified information” and is designated as “Tier 1,” or is “approved” and is designated as “Tier 2.” The term “generic,” means that if the Commission makes a change to the design certification,

§ 52.63(a) requires that the change (“modification” under § 52.63(a)(3)) be applied to each plant referencing the design certification rule.

A change to a design certification may be distinguished from a departure or variance by understanding that a change is generic. Therefore, a change to a design certification is:

- (1) Requested by the original design certification applicant in accordance with 10 CFR 2.811 (see 10 CFR 2.800(c)), or by any other member of the public, in a petition for rulemaking under 10 CFR 2.802;
- (2) Applies to all past nuclear power reactors (including manufactured reactors) whose applications have referenced the design certification, as well as future reactors referencing the design certification rule; and
- (3) Requires the Commission provide an exemption to the applicant, if the proposed change is inconsistent with the one or more of the Commission’s regulations.

Departure

A *departure* as a plant-specific “deviation” from design information in either a standard design certification or a manufacturing license. For a design certification, a departure is a deviation from the certification information which is certified by the Commission in a standard design certification rule (for the current four design certification rules in appendices A through D of part 52, the certification information is “Tier 1” information). For a manufacturing license, a departure is a deviation from any design information approved in the manufacturing license, including technical specifications, site parameters and design characteristics, and interface requirements.² A departure may be distinguished from a change to a standard design

²As discussed in the section-by-section discussion for § 52.171, a departure requested by a holder of a combined license referencing a manufactured reactor must be in the form of a license amendment, but the criteria for determining the request will be the exemption criteria in § 52.7 even though the departure itself may not involve an exemption.

certification rule (*i.e.*, a change to Tier 1 or Tier 2 information in a design certification rule) or a change to the design approved in a manufacturing license by recalling that a departure is *plant-specific*. Therefore, a departure:

- * Concerns certified design information or manufacturing license information.
- * Is requested by the applicant/licensee referencing a design certification or the use of a manufactured reactor.
- * Applies only to the design of the nuclear power reactor referencing the design certification or the manufactured reactor for which a departure is sought by the applicant/licensee.
- * Requires the applicant/licensee to obtain an exemption from the referenced design certification if the proposed departure is inconsistent with the one or more of the Commission's regulations. The exemption would be granted under the provisions of § 52.7 (which references the same criteria for the granting of exemptions that are set forth in § 50.12).

Variance

A *variance* is a plant-specific "deviation" from one or more of the site characteristics, design parameters, or terms and conditions of an early site permit, or from the site safety analysis report. A variance to an early site permit is analogous to a departure to a standard design certification, in that it is *plant-specific*. Therefore, a variance:

- (1) Concerns information addressed in an early site permit;
- (2) Is requested by the applicant referencing an early site permit;
- (3) Applies only to the construction permit or combined license referencing the early site permit; and
- (4) Requires the applicant to also obtain an exemption from the Commission's regulations if the proposed variance is inconsistent with one or more of the Commission's regulations.

Exemption

An *exemption* is a Commission-granted dispensation from compliance with one or more of the Commission's rules and regulations which would otherwise apply to an entity, a license, permit or other approval such as a standard design certification rule. Exemption from the requirements in part 26, or from the requirements in any particular design certification rule would be provided under § 52.7. Exemption from an underlying technical requirement in part 50 would be provided under § 50.12. This would be true even in the course of Commission adoption of a design certification rule. For example, if the design certification did not, at the time of final rulemaking, comply with a technical requirement in part 50, the Commission would provide an exemption to that requirement as part of the final design certification rulemaking. Moreover, if the nature of the technical requirement is such that a subsequent applicant referencing the design certification would need an exemption from compliance with the requirement as applied to the applicant, then the Commission would include the exemption in the design certification rule itself.

5. General Provisions.

a. Section 52.0, Scope; applicability of 10 CFR Chapter 1 provisions.

The Commission is redesignating former § 52.1, *Scope*, as § 52.0, *Scope; applicability of 10 CFR Chapter 1 provisions*, in order to add additional sections in the *General Provisions* portion of part 52. As discussed elsewhere, the Commission has decided general provisions, common to all substantive parts in 10 CFR Chapter 1, should be added to part 52. To provide enough section numbers, it is necessary to redesignate former § 52.1 as § 52.0.

Paragraph (a) of § 52.0 is derived from the text of former § 52.1, but is revised to include standard design approvals and manufacturing licenses within the scope of part 52, and to remove references to Section 104.b of Atomic Energy Act of 1954 (AEA), thereby providing that licenses issued under part 52 are licenses issued under Section 103 of the AEA. After passage of the 1970 amendments to the AEA, all licenses for commercial nuclear power plants with construction permits issued after the date of the amendments were required to be issued as Section 103 licenses. The NRC interprets the 1970 amendment as requiring combined licenses under Section 185 to be issued as Section 103 licenses.³ Accordingly, the NRC is revising the scope of part 52 to limit its applicability to licenses issued under Section 103 of the AEA.

Paragraph (b) of § 52.0 is a new provision that makes clear that the regulations in 10 CFR Chapter 1 apply to a holder of, or applicant for an approval, certification, permit, or license issued under part 52 and that any license, approval, certification, or permit, issued under 10 CFR part 52 must comply with these regulations. The need for this paragraph was determined as a result of the July 3, 2003 (68 FR 40026) proposed rule on part 52. In that proposed rule, the Commission proposed a new § 52.5 listing all of the licensing provisions in

³This may be an academic distinction, in light of the Energy Policy Act of 2005, Pub. L. No. 109-58, which removed the need for antitrust reviews of new utilization facilities.

10 CFR part 50 that also apply to all of the licensing processes in 10 CFR part 52. This proposal responded to a letter dated November 13, 2001, from the Nuclear Energy Institute (NEI), which stated:

The industry proposes that additional General Provisions be added to Part 52 in addition to an appropriate provision on Written Communications. This approach is preferable to including cross-references in Part 52 to Part 50 general provisions because these provisions typically must be tailored to apply appropriately to the variety of licensing processes in Part 52.

Section 52.5, as proposed in 2003, would have clarified that the general provisions in 10 CFR part 50 were also applicable to the new licensing processes for early site permits, standard design certifications, and combined licenses in part 52 (as well as the licensing and approval processes in appendices M, N, O, and Q which were added to part 52 by the 1989 part 52 rulemaking). Although the general provisions in part 50 did not specifically refer to the additional licensing processes in 10 CFR part 52 (and no changes to the language of those general provisions was proposed, the Commission believed that proposed § 52.5 would make clear that a holder of, or applicant for an approval, certification, permit, or license issued under part 52 must also comply with those general provisions.

However, few commenters on the July 2003 proposed rule believed that the proposed § 52.5 would provide greater clarity. On the contrary, some commenters indicated that § 52.5 was overly broad and would impose burdensome and seemingly inappropriate new requirements on applicants for design certifications that were unwarranted.

Accordingly, in the March 2006 proposed rule, the Commission proposed a different approach, *viz.*, making conforming changes to all of the regulations in 10 CFR Chapter 1 to specify their applicability to the relevant part 52 regulatory processes, and to add proposed § 52.0(b) to make clear that the regulations in 10 CFR Chapter 1 apply to the relevant part 52

regulatory processes, and holders and applicants under part 52. The Commission did not receive any comments calling into question the legality of this approach, or otherwise questioning the clarity of the proposed regulatory language. Accordingly, the Commission is adopting this approach in the final part 52, including § 52.0(b).

As discussed elsewhere in this statement of considerations, the NRC is retaining appendices N and Q in part 52, and revising these appendices to apply to part 52 combined licenses. The provisions of appendix N to part 52 concern applicants of combined licenses under part 52. Therefore, the applicability language in § 52.0, by referring to “licenses” under part 52, need not specifically refer to appendix N to part 52. Appendix Q to part 52 concerns an early site approval. Therefore, the applicability language in § 52.0, by referring to “approvals” under part 52, need not specifically refer to appendix Q to part 52.

b. Section 52.1, *Definitions*.

Section 52.1 (formerly, § 52.3) is revised by adding definitions for *decommission*, *license*, *licensee*, *major feature of the emergency plans*, *manufacturing license*, *modular design*, *prototype plant*, and *standard design approval*. A definition of *decommission*, which is identical to that in 10 CFR part 50, is added to part 52 because the final part 52 rulemaking addresses decommissioning of nuclear power reactors with combined licenses under part 52. Definitions of *license* and *licensee* are added to facilitate the use of these terms throughout part 52. These definitions were derived from the definitions in § 2.4, but were modified to reflect the regulatory processes in part 52. The definitions of these terms in part 2 are modified to be consistent with the definitions in part 52, and the definitions of these terms are added in part 50, to ensure consistency among parts 2, 50, and 52. Definitions of *manufacturing license*

and *standard design approval* are added to part 52 so that each of these part 52 license types are defined.

A definition of *modular design* is added to explain the type of modular reactor design which is the subject of the second sentence of § 52.103(g). That provision is added to part 52 to facilitate the licensing of nuclear plants, such as the Modular High Temperature Gas-Cooled Reactor (MHTGR) and Power Reactor Innovative Small Module (PRISM) designs, consisting of three or four nuclear reactors in a single power block with a shared power conversion system. During the period that the power block is under construction, the NRC could separately authorize operation for each nuclear reactor when each reactor and all of its necessary support systems were completed. In view of the several definitions of “modular reactor” which are used within the nuclear industry, the Commission intends to avoid future disputes regarding the intended applicability of § 52.103(g) by defining the term, *modular design*, for purposes of part 52.

The definition of *major feature of the emergency plans* is being added in the final rule, based on commenters’ responses to Question 2 in Section V of the Supplementary Information of the 2006 proposed rule, to clarify what is meant by this term as it is used in §§ 52.17, 52.18, 52.39, and 52.79. The definition states that a major feature of the emergency plans means an aspect of those plans necessary to: (1) address in whole or part, one or more of the sixteen standards in § 50.47(b), or (2) describe the emergency planning zones as required in § 50.33(g). The goal of the “major features” option in § 52.17(b) is an NRC finding that the proposed major features are acceptable as elements of a complete and integrated emergency plan that would be considered later, when the early site permit is referenced in a license application. This is not the same level of finality as the “reasonable assurance” finding that would be made in connection with the approval of a completed and integrated plan. However, the NRC would not re-review, at the COL stage, information that provided the basis for the NRC

approval of major features in an ESP but would address integration of approved major features with the balance of emergency planning information provided in the COL applications necessary to support the NRC's reasonable assurance finding; and updated emergency planning information required by § 52.39(b).

A definition of *prototype plant* is added to explain the type of nuclear power plant that the NRC is addressing in §§ 52.43, 52.47(b), 52.79, and 52.157. A *prototype plant* is a licensed nuclear reactor test facility that is similar to and representative of either the first-of-a-kind or standard nuclear plant design in all features and size, but may have additional safety features. The purpose of the prototype plant is to perform testing of new or innovative safety features for the first-of-a-kind nuclear plant design, as well as being used as a commercial nuclear power facility.

c. Section 52.2, *Interpretations*; and § 52.4, *Deliberate misconduct*.

The former section on interpretations in § 52.5 is retained and redesignated without change as § 52.2. The former section on deliberate misconduct in § 52.9 is retained and redesignated without change as § 52.4.

d. Section 52.3, *Written communications*; § 52.5, *Employee protection*; § 52.6, *Completeness and accuracy of information*; § 52.7, *Specific exemptions*; § 52.8, *Combining licenses*; § 52.9, *Jurisdictional limits*; and § 52.10, *Attacks and destructive acts*.

Section 52.3, *Written communications*, which is essentially identical with the current § 50.4, is added to address the requirements for correspondence, reports, applications, and other written communications from applicants, licensees, or holders of a standard design approval to the NRC concerning the regulations in part 52.

Section 52.5, which is largely identical with the current § 50.7, is added to make clear that discrimination against an employee for engaging in certain protected activities concerning the regulations in part 52 is prohibited. This section differs from its part 50 counterpart, in that the Commission has added a provision on coordination with the requirements in 10 CFR part 19.

Section 52.6, which is identical with the current § 50.9, is added to require that information provided to the Commission by a licensee, a holder of a standard design approval, and an applicant under part 52, and information required by statute or by the NRC's regulations, orders, or license conditions to be maintained by a licensee, holder of a standard design approval, and applicant under part 52 (including the applicant for a standard design certification under part 52 following Commission adoption of a final design certification rule) be complete and accurate in all material respects. The Commission has corrected an error in the proposed rule version of paragraph (a) of § 52.6. In the proposed rule, the first sentence began, "Information provided to the Commission by a licensee (including a construction permit holder, and a combined license holder)...." In the final rule, this phrase has been corrected to read, "Information provided to the Commission by a licensee (including an early site permit holder, a combined license holder, and a manufacturing license holder)...." This provision applies to licenses issued under part 52 and not to licenses issued under part 50.

Section 52.7, which is essentially identical with current § 50.12, is added to address the procedure and criteria for obtaining an exemption from the requirements of part 52. Although part 50 contains a provision (§ 50.12) for obtaining specific exemptions, § 50.12 by its terms

applies only to exemptions from part 50. Although it would be possible to revise § 50.12 so that its provisions apply to exemptions from part 52, this is inconsistent with the general regulatory structure of 10 CFR, wherein each part is treated as a separate and independent regulatory unit. The NRC notes that the exemption provisions in § 52.7 are generally applicable to part 52, and do not supercede or otherwise diminish more specific exemption provisions that are in part 52.

Section 52.8, which combines into a single section regulatory provisions which are addressed in separate regulations in part 50, is added to clarify that these regulatory provisions also apply to part 52 licenses.

Paragraph (a) of § 52.8, which is analogous to § 50.31, is added to make clear that an applicant for a license under part 52 may combine in one application, several applications for different kinds of licenses under various regulations in 10 CFR Chapter 1. Section 50.31 currently provides that an applicant may combine in one application, several applications for different kinds of licenses under various regulations in 10 CFR Chapter 1. The plain reading of this language, given that this provision is located in part 50, is that a *part 50* application may contain in one application other applications for different licenses in other parts of 10 CFR Chapter 1. Thus, § 50.31 would not appear to allow a *part 52* application (as for a combined license) to combine in one application other applications for different license in other parts of 10 CFR Chapter 1. Accordingly, paragraph (a) of § 52.8 of the final rule makes clear that a part 52 application may be combined with applications for different licenses in other parts of 10 CFR Chapter 1. This provision was not included in the March 2006 proposed rule, inasmuch as the NRC determined the desirability of including in part 52 a provision analogous to § 50.31 only after the publication of the March 2006 proposed rule.

Paragraph (b) of § 52.8, which is analogous to § 50.32, is added to make clear that an applicant for a license, standard design certification, or design approval under part 52 may

incorporate by reference in its application information contained in other documents provided to the Commission, but must clearly specify the information to be incorporated. This provision was also not included in the March 2006 proposed rule, inasmuch as the NRC determined the desirability of including in part 52 a provision analogous to § 50.32 only after the publication of the March 2006 proposed rule.

Paragraph (c) of § 52.8, which is analogous to § 50.52, is added to clarify the Commission's authority under Section 161.h of the AEA to combine NRC licenses, such as a special nuclear materials license under part 70 for the reactor fuel, with a combined license under part 52. Analogous to the situation with respect to § 50.31, the language in § 50.52 would not appear to allow the Commission to combine into a single part 52 license, other non-part 52 licenses. Inasmuch as these changes to § 52.8 constitute revisions to the Commission's rules of procedure and practice, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

Section 52.9, which is identical with § 50.53, is added to clarify that NRC licenses issued under part 52 do not authorize activities which are not under or within the jurisdiction of the United States; an example would be the construction of a nuclear power reactor outside the territorial jurisdiction of the United States which uses a design identical to that approved in a standard design certification rule in part 52.

Section 52.10 is added because there is no specific provision in part 52 specifying that the Commission's longstanding determination with respect to the lack of need for design features and other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by United States defense activities, applies to part 52 applicants. The Commission's determination, which was upheld by the U.S. Court of Appeals for the D.C. Circuit, see *Siegel v. Atomic Energy Commission*, 400 F.2d 778

(D.C. Cir 1968), is currently codified for part 50 applicants in § 50.13. Although it would be possible to revise § 50.13 so that its provisions apply to applications under part 52, this would be inconsistent with the overall regulatory pattern of 10 CFR Chapter 1, whereby each part is treated as a separate and independent regulatory unit. Moreover, any changes to § 50.13 might erroneously be viewed as changes to the Commission's substantive determination on this matter. For these reasons, the Commission is adding new § 52.10 to part 52, which is essentially identical with § 50.13. Inclusion of this provision in part 52 makes clear that applications for combined licenses, manufacturing licenses, design certification rulemakings, standard design approvals, and amendments to these licenses, rulemakings, and approvals under part 52 need not provide design features or other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by United States defense activities. In adding § 52.10, the Commission emphasizes that it is not changing in any way, nor is it intending to revisit in this rulemaking, the Commission's determination with respect to the lack of need for design features or other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by United States defense activities. The Commission is simply making it clear that its longstanding determination applies to applications under part 52 just as it applies to applications under part 50.

6. Subpart A, Early Site Permits.

a. Emergency Preparedness Requirements for Early Site Permit Applicants.

The NRC is amending §§ 52.17(b), 52.18, and 52.39 to address changes to emergency preparedness requirements for early site permit applicants. The NRC is amending § 52.17(b)(1), which requires that an early site permit application identify physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans. The NRC is adding a sentence to require that, if physical characteristics that could pose a significant impediment to the development of emergency plans are identified, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. The NRC believes this addition is necessary to clarify the NRC's expectations in cases where a physical characteristic exists that could pose a significant impediment to the development of emergency plans. Simply identifying these physical characteristics alone does not provide the NRC with enough information to determine if these characteristics are likely to pose a significant impediment to the development of emergency plans. Similarly, the Commission is amending § 52.18 to require that the Commission determine whether the information required of the applicant by § 52.17(b)(1) shows that there is no significant impediment to the development of emergency plans *that cannot be mitigated or eliminated by measures proposed by the applicant* [emphasis added].

The NRC is amending §§ 52.17(b)(2)(i), 52.17(b)(2)(ii), and 52.18 to clarify that any emergency plans or major features of emergency plans proposed by early site permit applicants must be in accordance with the applicable standards of 10 CFR 50.47 and the requirements of appendix E to part 50. These changes clarify the standards applicable to emergency preparedness information supplied with an early site permit application. The NRC is also amending §§ 52.17(b)(1), (b)(2), and (b)(4) to indicate that the emergency preparedness information supplied in the early site permit application must be included in the site safety analysis report. This change is necessary for consistency with past practice and with the requirements for combined license applicants in § 52.79(a) that require emergency

preparedness information to be included in the final safety analysis report. Note that the proposed rule only included these changes in § 52.17(b)(2). In the final rule, the NRC is making the additional conforming changes in §§ 52.17(b)(1) and (b)(4).

The NRC is adding new § 52.17(b)(3) to require that any complete and integrated emergency plans submitted for review in an early site permit application must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and would operate in conformity with the license, the provisions of the AEA, and the NRC's regulations. The NRC is making these amendments for consistency with the requirements in subpart C of part 52 regarding the review of emergency plans and to provide additional finality to ESP holders. The NRC believes that its review of complete and integrated plans included in an early site permit application should be no different than its review of emergency plans submitted in a combined license application, given that the NRC must make the same findings in both cases, namely, that the plans submitted by the applicant provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC will not be able to make the required finding without the inclusion of proposed ITAAC in an early site permit application that includes complete and integrated emergency plans. In the final rule, the NRC has added an allowance that major features of an emergency plan submitted under paragraph (b)(2)(i) of § 52.17 may include proposed ITAAC. This will give an applicant that has proposed major features additional opportunities to achieve finality on major features in cases where ITAAC can be included to address implementation aspects of the major feature.

b. Section 52.13, *Relationship to other subparts.*

The NRC proposes to retitle § 52.13 from “Relationship to subpart F of 10 CFR part 2 and appendix Q of this part,” to “Relationship to other subparts,” to reflect the revised scope of this section, which has been refocused on part 52.

c. Section 52.16, *Contents of applications; general information* and § 52.17, *Contents of applications; technical information.*

The NRC is adding § 52.16 to include the general content requirements from § 52.17(a)(1).

The title of § 52.17 is revised to read, “Contents of applications; technical information,” Section 52.17(a)(1) is amended to state that the early site permit application must specify the range of facilities for which the applicant is requesting site approval (*e.g.*, one, two, or three pressurized-water reactors). This new language, which is consistent with the language in paragraph 2 of current appendix Q to part 52, provides a clearer and more complete statement of the applicant’s proposal with respect to the facilities which may be located under the early site permit. This facilitates NRC review, as well as providing adequate notice to potentially-affected members of the public and State and local governmental entities. The NRC assumes that an applicant for an early site permit may not know what type of nuclear plant may be built at the site. Therefore, the application must specify the postulated design parameters for the range of reactor types, the numbers of reactors, etc., to increase the likelihood that approval of the site will resolve issues with respect to the actual plant or plants that the combined license or construction permit applicant decides to build. In a letter dated November 13, 2001

(comment 27 on draft proposed rule text), NEI stated, “The proposed change is too limited. To address the required assessment of major SSCs [structures, systems, and components] that bear on radiological consequences and all items 52.17.a.1.i-vii (sic.), industry recommends new § 52.17a.2.” The NRC disagrees with NEI’s proposal to have a separate provision for applicants who have not determined the type of plant that they plan to build at the proposed site. The NRC expects that some applicants for an early site permit may not have decided on a particular type of nuclear power plant, therefore, § 52.17(a)(1) was revised to address this situation.

The NRC is amending § 52.17(a)(1) to eliminate all references to § 50.34. The references to § 50.34(a)(12) and (b)(10) are removed because these provisions require compliance with the earthquake engineering criteria in appendix S to part 50 and are not requirements for the content of an application. The reference to § 50.34(b)(6)(v), which requires plans for coping with emergencies, is also being removed. All requirements related to emergency planning for early site permits are addressed in § 52.17(b) and other plans for coping with emergencies will be addressed in a combined license application. Finally, the reference to the radiological consequence evaluation factors identified in § 50.34(a)(1) is being removed and the requirements are included in § 52.17(a)(1). The NRC is modifying the existing requirement for early site permit applications to describe the seismic, meteorological, hydrologic, and geologic characteristics of the proposed site to add that these descriptions must reflect appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated. This addition is to ensure that future plants built at the site would be in compliance with general design criterion 2 from appendix A to part 50 which requires that structures, systems, and components important to safety be designed to withstand the effects of natural phenomena such as

earthquakes, tornadoes, hurricanes, floods, tsunamis, and seiches without loss of capability to perform their safety functions. The design bases for these structures, systems, and components are required to reflect appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated.

The NRC is adding several requirements to § 52.17(a)(1). A requirement is added to § 52.17(a)(1)(x) that applications for early site permits include information to demonstrate that adequate security plans and measures can be developed. This requirement is inherent in current § 52.17(a)(1) which states that site characteristics must comply with 10 CFR part 100. Section 100.21(f) states that site characteristics must be such that adequate security plans and measures can be developed. A new § 52.17(a)(1)(xi) is added to require early site permit applications to include a description of the quality assurance program applied to site activities related to the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. This change was made for consistency with changes to § 50.55 and appendix B to part 50. A discussion of these changes can be found in this section under the heading "Appendix B to Part 50."

An additional requirement is added to § 52.17(a)(1) that is taken from § 50.34(h), and that the NRC believes should be applicable to early site permits. Section 52.17(a)(1)(xii) requires that early site permit applications include an evaluation of the site against the applicable sections of the NRC's application and review guidance in effect 6 months before the docket date of the application. The SRP requirement currently exists for applicants for construction permits, operating licenses, and combined licenses. The NRC also believes it should be applicable to applicants for early site permits because they are partial construction

permits that can be referenced in applications for construction permits or combined licenses and because it will facilitate the NRC's review of the early site permit application.

The NRC also revised § 52.17(a)(1)(xii) to require that the applicant evaluate its site against the applicable sections of the regulatory guide on "Combined License Applications for Nuclear Power Plants" (currently DG-1145). By referring to both the review guidance (SRP) and application guidance, the NRC will ensure that future applications will conform with the latest guidance for application format and content, as well as the review criteria.

The NRC is making a change to § 52.17(a)(1) based on several comments on the proposed rule. The NRC is deleting the requirement in proposed § 52.17(a)(1)(x) that required ESP applicants to address impacts on operating units of constructing new units on existing sites, as well as include a description of the managerial and administrative controls to be used to assure that the limiting conditions of operation for existing units will not be exceeded. The NRC is deleting this requirement because it was contrary to the industry-NRC understanding documented in correspondence in 2003 regarding ESP Topic ESP-19 [see NEI letter dated May 14, 2003 (ML031920246), and NRC letter dated August 11, 2003 (ML031490478)] and because the COL applicant is in the best position to provide such information, since it will have final information regarding the facility design and construction plans. The NRC is considering whether to include a condition in early site permits that would require the permit holder to notify the operating plant licensee prior to conducting any activities authorized under § 52.25. These controls should be sufficient to evaluate construction activities at a site with an existing operating unit. The NRC has deleted this provision from subpart A in the final rule. COL applicants will, however, continue to be required to meet this provision under § 52.79(a)(31).

The NRC is moving the environmental provisions in former § 52.17(a)(2) to § 51.50(b). Revised § 52.17(a)(2) simply states that an early site permit application must contain a complete environmental report as required by 10 CFR 51.50(b). A discussion of the final rule

provisions related to the NRC's environmental review at the ESP stage can be found in the Supplementary Information section that discusses changes to 10 CFR part 51.

The NRC is amending § 52.21 to reflect clarifications provided in part 51 that an early site permit applicant has the flexibility of either addressing the matter of alternative energy sources in the environmental report supporting its early site permit application, or deferring consideration of alternative energy sources to the time that the early site permit is referenced in a licensing application. These changes to § 52.21 clarify that the NRC's EIS need not address the need for power or alternative energy sources (and therefore these matters may not be litigated) if the early site permit applicant chooses not to address these matters in its environmental report.

The NRC is amending § 52.17(c) to clarify that if the applicant wants to request authorization to perform limited work activities at the site after receipt of the early site permit, the application must contain an identification and description of the specific activities that the applicant seeks authorization to perform. This request by the early site permit applicant would be separate from, but not in addition to, a request to perform activities under 10 CFR 50.10(e)(1). The submittal of this descriptive information will enable the NRC staff to perform its review of the request, consistent with past practice, to determine if the requested activities are acceptable under § 50.10(e)(1). If an applicant for a construction permit or combined license references an early site permit with authorization to perform limited work activities at the site and subsequently decides to request authorization to perform activities beyond those authorized under § 52.24(c), those additional activities will have to be requested separately under § 50.10(e)(1). Some minor changes were made to the rule language in § 52.17(c) in the final rule to remove references to information being included in either the site safety analysis report or the environmental report. The NRC concluded that it is preferable to include both the list of proposed activities and the redress plan as a separate document in the application,

outside of both the site safety analysis report and the environmental report. The NRC's conclusion is based on the fact that the requirements in § 50.10(e) address both safety and environmental issues. Additional changes were made to §§ 51.50, 52.79(a), and 52.80 to implement this concept.

d. Section 52.24, *Issuance of early site permit.*

The NRC is revising § 52.24 to clarify the information that the NRC must include in the early site permit when it is issued. Section 52.24 is also being amended to be more consistent with the parallel provision in § 50.50, *Issuance of licenses and construction permits*, by requiring the NRC to ensure that there is reasonable assurance that the site is in conformity with the provisions of the AEA, and the NRC's regulations; that the applicant is technically qualified to engage in any activities authorized; and that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public.

Section 52.24 is being amended to provide that the early site permit must state the site characteristics and design parameters, as well as the "terms and conditions," of the early site permit, rather than the "conditions and limitations" as was formerly provided. The change provides consistency with § 52.39(a)(2), and in particular §52.39(a)(2)(iii) of the former regulations, which also refers to "site parameters" (corrected to "site characteristics" in the final rule) and "terms and conditions." Section 52.24(c) is being added to require that the early site permit state the activities that the permit holder is authorized to perform at the site. This change is consistent with the revision to § 52.17(c) where the applicant must specify the activities that it is requesting authorization to perform at the site under § 50.10(e)(1).

The NRC is revising paragraph (b) of this section based on public comments.

Paragraph (b) states that the early site permit shall specify the site characteristics, design parameters, and terms and conditions of the early site permit the NRC deems appropriate.

Paragraph (b) further states that, before issuance of either a construction permit or combined license referencing an early site permit, the Commission shall find that any relevant terms and conditions of the early site permit have been met. The NRC is revising this paragraph to add a provision that any terms or conditions of the early site permit that could not be met by the time of issuance of the construction permit or combined license, must be set forth as terms or conditions of the construction permit or combined license. This provision is needed to address terms or conditions of the early site permit that are related to activities that will not take place until after issuance of the construction permit or combined license, such as construction activities. A similar change is being made to § 52.79(b)(3).

e. Section 52.27, *Duration of permit.*

Section 52.27 provides for the duration of an early site permit. The NRC did not propose any changes to this section in the proposed rule. However, in the final rule, the NRC is making several revisions. First, the NRC is revising former § 52.27(b)(1) [final § 52.27(b)]. This paragraph states that an early site permit continues to be valid beyond the date of expiration in any proceeding on a construction permit application or a combined license application that references the early site permit and is docketed before the date of expiration of the early site permit, or, if a timely application for renewal of the permit has been filed, before the Commission has determined whether to renew the permit, consistent with the “Timely Renewal” doctrine of the Administrative Procedure Act. This section is changed in the final rule by

deleting the term, “filing,” and substituting the term, “docketing.” The NRC believes that timely renewal protection should only be provided to those applications which are of sufficient quality to be docketed. This is consistent with the requirement in § 2.109(b) requiring filing of a “sufficient” application for renewal of operating licenses as a prerequisite for the applicability of the timely renewal protection. Inasmuch as the changes to former § 52.72(b)(1) constitute revisions to the NRC’s rules of procedure and practice, the NRC may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

The NRC is also making revisions to § 52.27 based on public comments. The NRC is deleting proposed § 52.27(b)(2) because it was inconsistent with proposed § 52.39(d) and the NRC’s intention that the early site permit be subsumed into the construction permit or combined license once the construction permit or combined license is issued. To make this intention clear, the NRC is also adding new § 52.27(d) in the final rule. This provision states that upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license. By “subsumed” the NRC means that the information that was contained in the early site permit site safety analysis report (SSAR) becomes part of the referencing combined license final safety analysis report upon issuance of the combined license in the same manner as if the combined license applicant had not referenced an early site permit. The NRC is including the phrase “to the extent referenced,” to indicate that it is not all of the information submitted in the early site permit application that is subsumed into the combined license, but, only that information that is contained in the SSAR and identified by the applicant as being referenced in the combined license application. This subsumption of the early site permit into the referencing license affects the way changes to the early site permit information will be handled because it breaks the tie to the finality provisions in § 52.39. After issuance of the construction permit or

combined license, § 52.39 no longer applies to the early site permit information and such information will be covered by the same finality provisions as the rest of the information in the FSAR (with the exception of any referenced design certification information), as outlined in § 52.98 (e.g., in accordance with §§50.54, 50.59, etc.).

f. Section 52.28, *Transfer of early site permit.*

Section 52.28 is being added to state that transfer of an early site permit from its existing holder to a new applicant would be processed under § 50.80, which contains provisions for transfer of licenses. In a letter dated November 13, 2001 (comment 19 on draft proposed rule text), the NEI recommended that a new section be added to part 52 to clarify the process for transfer of an early site permit. The NRC has determined that a new section is not necessary because an early site permit is a partial construction permit and, therefore, is considered to be a license under the AEA. The NRC believes that the procedures and criteria for transfer of utilization facility licenses in 10 CFR 50.80 (and the procedures in subpart M of part 2 for the conduct of any hearing) should apply to the transfer of an early site permit. Changes that the NRC has made to § 50.80 in the final rule to address comments made regarding requirements for transfer of an early site permit can be found in Section V.D.8.a of the Supplementary Information of this document.

g. § 52.33, *Duration of renewal.*

Section 52.33 has been revised in the final rule to clarify that the renewal period for an early site permit includes any remaining years on the early site permit then in effect before

renewal. This change was made to be consistent with the NRC's regulations concerning renewal of nuclear power plant operating licenses as specified in § 54.31 of this chapter.

h. Section 52.37, *Reporting of defects and noncompliance; revocation, suspension, modification of permits for cause.*

Section 52.37 is removed because this provision only contains a cross-reference to 10 CFR part 21 and § 50.100, and the NRC is making conforming changes to those requirements to account for requirements for early site permits.

i. Section 52.39, *Finality of early site determinations.*

The NRC is revising § 52.39 to address the finality of an early site permit. While some of the changes are conforming or clarifying, others represent a change from the finality provisions in the former § 52.39. Paragraph (a)(2) of the former rule distinguishes among issues alleging that: (1) a “reactor does not fit within one or more of the site parameters,” which are to be treated as valid contentions (paragraph (a)(2)(i)); (2) a “site is not in compliance with the terms of an early site permit,” which are to be subject to hearings under the provisions of the Administrative Procedure Act (paragraph (a)(2)(ii)); and (3) the “terms and conditions of an early site permit should be modified,” which are to be processed in accordance with 10 CFR 2.206(a)(2)(iii). With the benefit of hindsight and experience gained in reviewing the first three early site permit applications, the NRC believes that all issues concerning a referenced early site permit may be characterized as:

- (1) Questions regarding whether the site characteristics, design parameters, or terms and conditions specified in the early site permit have been met;

- (2) Questions regarding whether the early site permit should be modified, suspended, or revoked; or
- (3) Significant new emergency preparedness or environmental information not considered on the early site permit.

Questions about the referencing application demonstrating compliance with the early site permit are fundamentally questions of compliance with the early site permit. They do not attack the underlying validity of the permit. For example, if a person questions whether the design characteristics of the nuclear power facility that the referencing applicant proposes to construct on the site falls within the design parameters specified in the early site permit, it is a matter of compliance with the early site permit. These compliance matters are specific to the proceeding for the referencing application, and the NRC concludes that adequately question supported about whether the referencing application complies with the early site permit may be viewed as question/material to the proceeding and appropriate consideration in the referencing application proceeding (assuming that all relevant Commission requirements in 10 CFR part 2, such as standing and admissibility, are met).

The NRC also regards new emergency preparedness information submitted in the referencing application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness as an issue material to the proceeding and appropriate for consideration as a contention in the referencing application proceeding (assuming that all relevant Commission requirements in 10 CFR part 2, such as standing and admissibility, are met. This is a change to the standard that was provided in the proposed rule for new emergency preparedness information and is based on public comments. The proposed rule standard for litigation of emergency preparedness matters was “new or additional information...which materially affects the Commission’s earlier determination on emergency

preparedness, or is needed to correct inaccuracies in the emergency preparedness information approved in the early site permit.” Because the final rule language suggested by the commenters is the definition that the NRC gave for information that could “materially affect” the Commission’s earlier decision, as indicated in the Supplementary Information section of the 2006 proposed rule, the NRC believes it appropriate to use this language in the final rule itself. The NRC has decided to drop the language that referred to information “needed to correct inaccuracies” because the language, by itself, could have allowed litigation of issues not significant to safety. The NRC believes that the final rule language encompasses all significant emergency preparedness matters that should be subject to litigation.

Any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified may also be the subject of a contention during the proceeding on the referencing application. The NRC is also making a change to this standard in the final rule based on public comment. The standard in the final rule more closely reflects the NRC’s obligation under NEPA to address new and significant information in a COL that references an early site permit. Additional discussion of this subject can be found in the discussion of changes in 10 CFR part 51, in the Supplementary Information section of this document.

Because new emergency planning or environmental information, if any, will be identified only at the time a license application referencing the early site permit is submitted to the NRC, the NRC believes it is appropriate to address these issues in the proceeding on the referencing application. Other questions regarding whether the permit should be modified, suspended, or revoked will be challenges to the validity of the early site permit. These challenges may be framed in many different ways, *e.g.*, a Commission error at the time of issuance; or actual changes to the site have occurred since issuance of the permit that render some aspect of the

permit irrelevant or inadequate to protect public health and safety or common defense and security. The Commission's process for challenges to the validity of a license is contained in 10 CFR 2.206. Accordingly, the Commission concludes that challenges to the validity of an early site permit should be processed in accordance with § 2.206. In the Commission's view, a variance is not fundamentally a challenge to the validity of the early site permit, because it requests dispensation from compliance with some aspect of the permit whose validity remains undisputed. Therefore, the Commission concludes that variances should be treated as proceeding-specific issues of compliance that are potentially valid subjects of a contention in a proceeding for a referencing application.

The revisions to § 52.39 are in agreement with these Commission conclusions. Section 52.39 is being divided into five paragraphs addressing different aspects of early site permit finality. Each paragraph is provided with a subtitle characterizing the subject matter addressed in that paragraph. Section 52.39(a) focuses on how the NRC accords finality to an early site permit, with § 52.39(a)(1) setting forth the circumstances under which the NRC may modify an early site permit. The rule language is based upon the existing regulation, but adds additional circumstances. Section 52.39(a)(1)(iii) provides that the NRC may modify the early site permit if it determines a modification is necessary based on an update to the emergency preparedness information under § 52.39(b). Section 52.39(a)(1)(iv) provides that the NRC may modify the early site permit if a variance is issued under proposed § 52.39(d) (paragraph (b) in the former regulations); the NRC considers this a conforming change inasmuch as the former regulation provided for issuance of variances.

The NRC is clarifying what aspects of the early site permit are subject to the change restrictions in § 52.39(a)(1) by substituting the phrase, "terms and conditions" of an early site permit for the former term, "*requirements*." Under the new language, the NRC may not change or impose new site characteristics, design parameters, or terms and conditions on the early site

permit, including emergency planning requirements, unless the special backfitting criteria in § 52.39(a)(1) are satisfied. No substantive change is intended by this clarification; the language would specify more clearly the broad scope of matters in an early site permit which the NRC intended to finalize. The phrase, “site characteristics, or terms, or conditions, including emergency planning requirements,” is used consistently throughout § 52.39 and corresponding provisions in the revisions to § 52.79.

Section 52.39(a)(2) describes how the NRC treats matters resolved in the early site permit proceeding in subsequent proceedings on applications referencing the early site permit, and is drawn from the former language of § 52.39(a)(2). In the final rule, the NRC has included a provision extending this finality to enforcement hearings other than those proceedings initiated by the Commission under paragraph (a)(1) of this section. This will ensure that finality of an early site permit extends to NRC-initiated enforcement proceedings and petitions for enforcement action filed under § 2.206. In addition, under §§ 52.39(a)(2)(i) and (ii), the NRC grants finality to changes to an early site permit’s emergency plan (or major features of it, under § 52.17(b)(2)) that are made after the issuance of the early site permit (1) if the early site permit approved an emergency plan (or major features thereof) that is in use by a licensee of a nuclear power plant and the changes to the emergency plan (or major features thereof) are identical to changes made to the licensee’s emergency plans in compliance with § 50.54(q); or (2) if the early site permit approved an emergency plan (or major features thereof) that is not in use by a licensee of a nuclear power plant, and the changes are equivalent to those that could be made under § 50.54(q) without prior NRC approval had the emergency plan been in use by a licensee. This change is premised on the view that changes to emergency plans which are properly implemented under § 50.54(q) do not require NRC review and approval before implementation. Therefore, by analogy, similar changes to an early site permit’s emergency preparedness plan made with similar controls, or changes which are equivalent to those that

could be made under § 50.54(q) without prior NRC approval, should not require NRC review and approval as part of the licensing process. Any issues related to compliance with § 50.54(q) should be treated as an enforcement matter. Note that the NRC is making some adjustments to this position in the final rule based on public comments. The proposed rule would not have excepted changes to early site permit emergency plans not in use by a current licensee that could be made under § 50.54(q) without prior NRC approval had the emergency plans been in use by a licensee. The NRC is making this change in the final rule because the § 50.54(q) standard ensures adequate protection of safety, and has been accepted and used by the industry and NRC and it is appropriate to apply this same standard to changes in all emergency plans approved by the NRC in the ESP proceeding. The NRC is making similar changes to § 52.79(b)(4) in the final rule to require that all COL applicants referencing early site permits with complete and integrated emergency plans or major features of emergency plans identify changes that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a decrease in effectiveness under § 50.54(q) of this chapter.

Section 52.39(b) is discussed separately under Section V.C.6.a of this document, which discusses emergency preparedness requirements for a combined license applicant referencing an early site permit.

Section 52.39(c) replaces the former criteria in §§ 52.39(a)(2)(i) through (iii), governing how the NRC will treat various issues with respect to the early site permit and its referencing in a combined license application. Matters regarding compliance with the early site permit which would be potentially valid subjects of a contention are listed in §§ 52.39(c)(1)(i) through (iii), e.g., whether the reactor proposed to be built under the referencing application fits within the site characteristics and design parameters specified in the early site permit; whether one or more of the terms and conditions of the early site permit have been met; and whether a variance requested by the referencing applicant is unwarranted or should be modified. Matters

regarding significant new emergency preparedness or environmental information material to the combined license proceeding, which would be potentially valid subjects of contention under the proposed rule, are listed in §§ 52.39(c)(1)(iv) and (v).

Other matters, including changes to the site characteristics, design parameters, or terms and conditions of the early site permit, are treated under § 52.39(c)(2) as challenges to the permit and processed in accordance with § 2.206. The NRC is retaining the former provision in § 52.39(a)(2)(iii) requiring that the Commission consider a petition filed under § 2.206, and determine whether immediate action is required before construction commences, as well as the former provision indicating that if a petition is granted, the Commission will issue an appropriate order which does not affect construction unless the Commission makes its order immediately effective.

The final rule redesignates the former provision in § 52.39(b) allowing an applicant for a license referencing an early site permit to request a variance from one of more “elements” of the early site permit as § 52.39(d). The rule clarifies “elements” for which a variance may be sought by substituting the phrase, “site characteristics, design parameters, or terms and conditions of the early site permit.” In addition, the NRC is revising this provision further to include an allowance for applicants to request a variance from the site safety analysis report (SSAR). The allowance for requesting variances to the SSAR was inadvertently omitted in the proposed rule. Because the majority of the early site permit information that a combined license applicant will be referencing will be the information in the SSAR, it is logical that the allowance to request variances be extended to the information in the SSAR given that the NRC is allowing variances to the permit itself. The NRC notes that the admission of a contention on a proposed variance, which was formerly addressed in § 52.39(b), is addressed in § 52.39(c)(iii). The NRC is also adding a provision that precludes the Commission from issuing a variance once a construction permit or combined license referencing the early site permit is

issued. Any changes that would otherwise require a variance should instead be treated as an amendment to the construction permit or combined license.

Finally, the NRC is adding a new paragraph to the “finality” section in each subpart of part 52, in this instance § 52.39(f), entitled “Information requests,” which delineates the restrictions on the NRC for information requests to the holder of the early site permit. This provision is analogous to the former provision on information requests in paragraph 8 of appendix O to parts 50 and 52, and is based upon the language of § 50.54(f). For early site permits, this provision is contained in § 52.39(d), and requires the NRC to evaluate each information request on the holder of an early site permit to determine that the burden imposed by the information request is justified in light of the potential safety significance of the issue to be addressed in the information request. The only exceptions would be for information requests seeking to verify compliance with the current licensing basis of the early site permit. If the request is from the NRC staff, the request would first have to be approved by the Executive Director for Operations (EDO) or his or her designee.

7. Subpart B, Standard Design Certifications.

a. Section 52.41, *Scope of subpart.*

This section defines the scope of subpart B of part 52. The requirements on scope and type of nuclear power plants that are eligible for design certification were moved from former § 52.45(a) to this section, to ensure a consistent format and presentation among all the subparts of part 52.

b. Section 52.43, *Relationship to other subparts.*

This section defines the relationship of subpart B to other subparts in 10 CFR part 52. Conforming changes were made to make clear that an application for a manufacturing license may, but is not required to, reference a design certification rule (DCR). The requirements formerly located in §§ 52.43(c), 52.45(c), and 52.47(b)(2)(ii) were removed because the Commission decided not to require a final design approval (FDA) under subpart E as a prerequisite for certification of a standard plant design. This requirement was included in part 52, at the time of the original rulemaking, because the NRC had no experience with design certifications. By requiring an FDA as a prerequisite to design certification, the NRC indicated that the licensing processes for design certifications and FDAs were similar, even though the requirements for and finality of a design certification differ from that of an FDA. The NRC now has considerable experience with design certification reviews, and the former requirement to apply for an FDA as part of an application for design certification is no longer needed. Future applicants have the option to apply for either an FDA, a design certification, or both.

c. Section 52.45, *Filing of applications.*

This section presents the requirements for filing design certification applications. This section was reformatted for consistency with the other subparts in part 52 and the references to specific paragraphs within §§ 50.4 and 50.30 were replaced with references to subpart H of part 2. A new § 52.45(c) on design certification review fees, was moved from § 52.49.

d. Section 52.46, *Contents of applications; general information.*

This section was added to set forth general content requirements from 10 CFR 50.33.

e. Section 52.47, *Contents of applications; technical information.*

This section presents the requirements for contents of a design certification application and is organized into three sections. The requirements for the final safety analysis report (FSAR) are set forth in §§ 52.47(a) and 52.47(c), and the technical requirements for the remainder of the design certification application are in § 52.47(b). The former § 52.47(a)(1)(i) required the submittal of information required for construction permits and operating licenses by parts 20, 50 (including the applicable requirements from 10 CFR 50.34), 73, and 100, which were technically relevant to the design and not site-specific. That general requirement was removed and replaced with specific requirements that describe what must be included in an FSAR. In addition, the NRC included technical positions that were developed after part 52 was originally codified in 1989, e.g., § 52.47(a)(22) which requires a description of how relevant operating experience was incorporated into the standard design (see SRM on SECY-90-377, dated February 15, 1991, ML003707892). Also, the relevant requirements were revised to clarify their applicability to design certifications and renumbered. This effort resulted in a comprehensive list of requirements for a design certification application.

Some commenters recommended that the requirement to demonstrate technical qualifications [now § 52.47(a)(7)] be deleted because the AEA only imposes that requirement on applicants for a license. Although the NRC agrees that the AEA imposes the technical qualification finding specifically for license applicants, it does not preclude the NRC from a determination that such a finding is also necessary in other contexts. The applicant creates information that may become the bases for a future license and, therefore, must be qualified to

perform design, analyses, and safety determinations. Accordingly, the NRC has concluded that a technical qualification finding should also be made for design certification applicants.

Some commenters recommended that the requirement to address the standard review plan (SRP) be revised to apply to light-water reactors. The NRC agrees with this comment and has revised this requirement [now § 52.47(a)(9)] to be applicable to light-water cooled nuclear power plants, but notes that much of the review guidance and criteria are general and would also apply to reviews of gas-cooled reactor designs. The NRC also revised § 52.47(a)(9) to require that the applicant evaluate its plant design against both the review guidance (SRP) and the applicable sections of the regulatory guide on “Combined License Applications for Nuclear Power Plants” (currently DG-1145). By referring to both the review guidance and application guidance, the NRC will ensure that future applications will conform with the latest guidance for application format and content, as well as the review criteria.

Some commenters recommended that the requirement to provide information required by § 50.49(d) [now § 52.47(a)(13)] be deleted because the applicant will not be able to establish qualification files for all applicable components. The NRC agrees that applicants may not be able to establish qualification files, but applicants can provide the electric equipment list required by § 50.49(d). Therefore, the NRC revised the wording in § 52.47(a)(13) to be consistent with the wording for the same provision in § 52.79(a), which requires that applicants provide the list of electrical equipment important to safety required by § 50.49(d).

Some commenters recommended that the requirement to demonstrate how operating experience insights have been incorporated into the plant design [now § 52.47(a)(22)] be deleted. The NRC disagrees with this comment. The NRC developed this requirement for future plants (see SRM on SECY-90-377) and it was implemented in past design certification applications by addressing generic letters and bulletins. The NRC agrees that insights from generic letters and bulletins should be incorporated into the latest revision of the standard

review plan and has revised this requirement accordingly. Regarding the requirement to address comparable international operating experience, the NRC understands that some future applications may be for designs that are not based on or are evolutions of plants that have operated in the United States. The NRC expects those applications to address how insights from relevant international operating experience have been incorporated into that design.

Some commenters recommended that the requirement to describe severe accident design features in the FSAR [now § 52.47(a)(23)] be deleted. The NRC disagrees with this comment because the Commission has determined that this requirement is necessary for future light-water reactor designs (see SRM on SECY-93-087) and was applied to previous applications. The commenters confused the meaning of design bases information (see § 50.2) with the requirements for design-basis accidents (DBAs). Postulated severe accidents are not design-basis accidents and the severe accident design features do not have to meet the requirements for DBAs (see SECY-93-087). However, the severe accident design features are part of a plant's design bases information.

A new § 52.47(b) was created to set forth the required technical contents of a design certification application that are not required to be located in the FSAR. In response to public comments on the proposed rule, the NRC has deleted proposed § 52.47(b)(1) which required design certification applicants to submit a design-specific probabilistic risk assessment (PRA). In its place, the NRC has added new § 52.47(a)(27) which requires that design certification applicants submit a description of the design-specific PRA and its results in the FSAR. The NRC agrees with some commenters that applicants should not be required to submit their complete design-specific PRA and that, instead, applicants should only be required to provide a summary description of the PRA and its results in their FSAR with the understanding that the complete PRA (*e.g.*, codes) would be available for NRC inspection at the applicant's offices, if needed. The NRC expects that, generally, the information that it needs to perform its review of

the design certification application from a PRA perspective is that information that will be contained in applicants' FSAR Chapter 19.

The rule language for ITAAC [now § 52.47(b)(1)] was conformed with the statutory language in the AEA. This clarification of the language in the former § 52.47(a)(1)(vi), which was a condensed version of the language in the current §§ 52.80(a) and 52.97(b), was intended to avoid any misunderstandings regarding the statutory requirement. Some commenters recommended that the rule language in § 52.47(b)(1) be modified to maintain the language in the former § 52.47(a)(1)(vi) claiming the proposed language could be misconstrued as expanding the scope of ITAAC needed for design certification. The NRC disagrees with this comment and notes that it is well understood that the requirements that are applicable to design certification are limited to the scope of the certified design.

Some commenters recommended that the requirement in § 52.47(b)(3) to evaluate severe accident mitigation design alternatives (SAMDA) be deleted and that the NRC should initiate a rulemaking or policy statement to disposition SAMDA generically. The NRC disagrees with this comment. The NRC has required SAMDA evaluations for previous applications in order to achieve greater finality for the design features that are resolved in design certification rulemakings. Further, the initiation of a rulemaking or policy statement for SAMDAs is outside the scope of the part 52 update rulemaking. As for the perspective that SAMDA evaluations need not be performed for current reactor designs because the severe accident risk for such designs is too remote and speculative. The NRC has already addressed this issue in other contexts. The NRC has considered petitions to eliminate the consideration of SAMDAs previously. The NRC position, both then and now is that it is not prepared to reach the conclusion that the risks of all severe accidents are so unlikely as to warrant their elimination from consideration in our NEPA reviews. As the NRC has stated in response to other requests to confine or eliminate such issues from consideration, if new information in the future provides

a firm basis for concluding that severe accidents are remote and speculative, then the NRC may revisit the issue.

Former § 52.47(b) was reorganized by separating the requirements on scope of design and modular configuration [now located in § 52.47(c)] from the testing requirements. This action is part of the NRC's goal to put the procedural requirements for the licensing processes in part 52 and maintain the reactor safety requirements in part 50 (or other parts of 10 CFR Chapter 1. As a result, the testing requirements were relocated to § 50.43(e). Also, see the discussion on testing for advanced nuclear reactors in Section V.B of this document.

f. Section 52.54, *Issuance of standard design certification.*

This section was amended to be consistent with the parallel provisions in §§ 50.50 and 50.57 by including requirements that, after conducting a rulemaking proceeding and receiving the report submitted by the ACRS, the NRC will determine whether there is reasonable assurance that the design conforms with the provisions of the AEA, and the NRC's regulations; that the applicant is technically qualified; and that issuance of the design certification will not be inimical to the common defense and security or to the health and safety of the public. In addition, a new § 52.54(a)(8) was added to state that the NRC will not issue a design certification unless it finds that the design certification applicant has implemented the quality assurance program described in the safety analysis report. This requirement was added to indicate the NRC's expectation that design certification applicants will implement the QA program that is required to be included in their application under § 52.47(a)(19), which is consistent with the requirement for licensees.

A new § 52.54(b) was added to require that a design certification specify the site parameters and design characteristics and any additional requirements and restrictions of the rule, as the Commission deems necessary and appropriate. Some commenters recommended that the requirement in § 52.54(b) to list “design characteristics” be removed and noted that the design control document will contain this information. The NRC disagrees with this comment. The NRC wants to specifically identify this information to facilitate future comparisons with “design parameters” specified in an early site permit. The NRC staff will use its experience with current early site permit reviews to determine what an appropriate list will be for future design certification reviews.

The NRC also modified § 52.54 to require that applicants for a design certification agree to withhold access to National Security Information from individuals until the requirements of 10 CFR parts 25 and/or 95, as applicable, are met. Section 52.54 was amended to include a new paragraph (c) which requires that every DCR contain a provision stating that, after the Commission has adopted the final design certification rule, the applicant for that design certification will not permit any individual to have access to, or any facility to possess, Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The NRC believes that this amendment, along with the changes to parts 25, 95, and 10 CFR 50.37, are necessary to ensure that access to classified information is adequately controlled by all entities applying for NRC certifications.

g. Section 52.63, *Finality of standard design certifications.*

The final rule revises the former special backfit requirements in § 52.63(a)(1) to provide the NRC with the ability to make generic changes to the DCRs or the certification information that reduce unnecessary regulatory burdens [see § 52.63(a)(1)(iii)]. The former § 52.63(a)(1) stated that the Commission may not modify, rescind, or impose new requirements on the certification unless the change is: (1) necessary for compliance with Commission regulations applicable and in effect at the time the certification was issued; or (2) necessary to provide adequate protection of the public health and safety or common defense and security. This regulation did not appear to permit changes to the certification which reduce unnecessary regulatory burdens in circumstances where the change continues to maintain protection to public health and safety and common defense and security. An example of a change which could not be made under the former § 52.63(a)(1) was a change to the DCRs in appendices A, B, and C of part 52, to incorporate into the Tier 2 change process the revised change criteria in 10 CFR 50.59. Section 50.59 was revised in 1999 to provide new criteria for, *inter alia*, making changes to a facility, as described in the final safety analysis report, without prior NRC approval, to reduce unnecessary regulatory burden (64 FR 53582, October 4, 1999).

The final rule includes a new provision [§ 52.63(a)(1)(iii)] that explicitly allows the NRC to change the DCRs in part 52 to reduce unnecessary regulatory burden, *i.e.*, incorporate the revised § 50.59 change criteria, or change the certification information if the change provides a reduction in regulatory burden and maintains protection to public health and safety and common defense and security. Maintaining protection generally embodies the same safety principles used by the NRC in applying risk-informed decision-making, *e.g.*, ensuring that adequate protection is provided, applicable regulations are met, sufficient safety margins are maintained, defense-in-depth is maintained, and that any changes in risk are small and consistent with the Commission's Safety Goal Policy Statement.

Section 52.63(a)(1) was also revised to replace “a modification” with “the change,” to clarify that the criteria for changes apply to modifications, rescissions, or imposition of new requirements. Also, § 52.63 was amended to be consistent with its original intent (refer to 54 FR 15372; April 18, 1989) that the special backfit requirements apply to the certification information, not to the “procedural and administrative” provisions in the DCRs, e.g., Section VI.E of appendix A to part 52. Any proposed changes to these “procedural and administrative” provisions that set forth how the DCRS are to be used will be controlled by the backfit requirements in 10 CFR 50.109.

In Section V of the 2006 proposed rule, question #14, the NRC stated that it was considering adopting an additional provision in § 52.63(a)(1) that would allow amendments of DCRs to incorporate generic resolutions of design acceptance criteria (DAC) or other design information without meeting the special backfit requirement in the former § 52.63(a)(1). By allowing for a DCR amendment to generically resolve DAC, the NRC would achieve resolution of additional design issues, would achieve finality for those issue resolutions, and would avoid repetitive consideration of those design issues in individual combined license proceedings. The NRC has decided to include an amendment process in § 52.63(a)(1) that will allow for generic resolutions of DAC without meeting the special backfit requirement. These amendments will apply to all plants that have or will reference the design certification rule under § 52.63(a)(2). The NRC believes that these amendments will enhance standardization by further completing the certification information. The NRC staff will review the amendment application to ensure that the design acceptance criteria are met and that the new design information conforms with the applicable regulations. For those design certifications that used the two-tiered rule structure, generic changes (amendments) to both Tier 1 and Tier 2 information are requested under 10 CFR 52.63(a)(1).

Many commenters encouraged the NRC to adopt an amendment process that would allow for “beneficial” changes to certification information, would apply the amendment to all plants referencing the certified design, and would only allow amendments prior to issuance of the first combined license that referenced the DCR. The NRC does not agree with the proposal to allow amendments to “beneficial” changes. The commenter’s proposed criterion could result in endless debates over what constitutes a beneficial change and may restrict future standardization benefits. Also, the NRC does not agree with precluding amendments after issuance of the first combined license. If licensees who referenced a DCR want to adopt a proposed amendment in order to achieve the enhanced standardization that the amendment would bring, then the NRC would codify the amendment and apply it to all plants referencing the DCR.

Some commenters also proposed that the amendment process allow for generic resolutions of errors in the certification information. The NRC is aware that applicants for design certification have discovered errors in their designs after the NRC has completed its review of the design information and even after the NRC has certified their design. The NRC wants to correct the applicant’s design errors and any NRC review errors, then resolve them generically so that these errors will not have to be addressed in individual licensing proceedings. Therefore, the NRC has included a new provision to correct errors in the certification information [see § 52.63(a)(1)(v)]. In the future, when the NRC receives a petition to amend a DCR, the NRC will use the new review opportunity to ensure that the certification information is in conformance with applicable regulations in effect at the time of the certification or last renewal, as applicable, and correct any errors that are identified by the petitioner or discovered by the NRC staff.

In addition, some commenters requested that the new amendment process allow for changes to the certification information for a wide variety of other reasons. These commenters

claimed that the need for a design change may be discovered during detailed design work performed after the original design information was approved by the NRC (so-called first-of-a-kind-engineering) or that certain components in the original design may no longer be available for purchase due to the long duration of a DCR. The NRC's deliberations on this proposal considered the Commission's goal for design certification, which is to achieve and maintain the benefits of standardization. The Commission stated in the original part 52 (April 18, 1989; 54 FR 15372) that achievement of the enhanced safety, which standardization makes possible, will be frustrated if too frequent changes to either a certified design or the plants referencing it are permitted. As a result, the former § 52.63(a)(1) contained a special backfit requirement to restrict changes and to require that everyone meet the same backfit standard for generic changes, thereby ensuring that all plants built under a referenced DCR would be standardized. The NRC is still determined to achieve the benefits of standardization, but has decided to allow amendments for other design changes provided that the amendment will be applied to all plants that reference the DCR. In determining whether to codify a proposed amendment, the NRC will give special consideration to comments from applicants or licensees who reference the DCR regarding whether they want to backfit their plants with these additional design changes.

The final rule revised § 52.63(a)(2) to delete the reference to § 52.63(a)(4). The reference to § 52.63(a)(4) was in error because this paragraph discusses the finality of the findings required for issuance of a combined license or operating license, whereas § 52.63(a)(2) deals with modifications that the NRC may impose on a DCR under §§ 52.63(a)(3) or 52.63(b)(1). No substantive change is intended by this revision, which merely clarifies the original intent of the rule.

Finally, the NRC has decided to reinforce its previous decision regarding the ability of any person to request an amendment to a DCR. In Section II.1.h of the 1989 SOC for part 52 (54 FR at 15372), the Commission stated that § 52.63(a)(1) places a designer on the same

footing as the NRC or any other interested member of the public. Therefore, anyone may submit a petition for rulemaking to the NRC to correct an error or otherwise amend the certification information. All amendments to the certification information must be accomplished through rulemaking, with an opportunity for public comment, under § 52.63(a)(2). Once a certified design is amended by rulemaking, the new rule would apply to all applications referencing the DCR as well as all plants referencing the DCR, unless the change has been rendered “technically irrelevant” through other action taken under §§ 52.63(a)(3) or (b)(1). Also, the NRC will decide whether to codify the proposed amendment based on comments from the referencing applicants and licensees. Thus, standardization is maintained by ensuring that any generic change to certification information intended to reduce regulatory burden or otherwise amend the original design are imposed upon all nuclear power plants referencing the DCR. The duration of the amended DCR will remain the same as the original DCR.

8. Subpart C, Combined Licenses.

a. Emergency Preparedness Requirements for a Combined License Applicant Referencing an Early Site Permit.

The NRC is revising former §§ 52.39 and 52.79 to require a license applicant referencing an early site permit to update and correct the emergency preparedness information provided under § 52.17(b). The issue of updating an early site permit was first raised by the Illinois Department of Nuclear Safety, who suggested in a September 28, 1994, letter that emergency plans and/or offsite certifications approved as part of an early site permit review be

kept up-to-date throughout the duration of an early site permit and the construction phase of a combined license.

In SECY-95-090, "Emergency Planning Under 10 CFR Part 52" (April 11, 1995), the NRC staff stated that 10 CFR part 52 does not clearly require an applicant referencing an early site permit to submit updated information on changes in emergency preparedness information or in any emergency plans that were approved as part of the early site permit in accordance with § 52.18. SECY-95-090 indicated (p. 4) that, in view of the lack of industry interest in pursuing an early site permit, resolution of this matter could be deferred until a "lessons learned" rulemaking updating 10 CFR part 52 was conducted after the first design certification rulemakings were issued. Following public release of a draft SECY paper setting forth the NRC staff's preliminary views on the licensing process for a combined license, NEI submitted a letter dated September 8, 1998 (comment 2.d), which expressed opposition to a requirement for updating emergency preparedness information throughout the duration of an early site permit, absent an application referencing the early site permit. As an alternative to updating throughout the duration of an early site permit, NEI proposed that emergency planning information be updated when an application for a license referencing the early site permit is filed; portions of the emergency plans that are unchanged would continue to have finality under 10 CFR 52.39. In a September 3, 1999, letter, the NRC staff identified updating of emergency preparedness information in early site permits as a possible subject for the part 52 rulemaking.

The NRC agrees in part with the Illinois Department of Nuclear Safety. Emergency plans and/or offsite certificates in support of emergency plans, approved as part of an early site permit review, should be updated. However, emergency plans do not need to be kept up-to-date throughout the duration of an early site permit. There is no need to update the emergency plans approved in an early site permit until the time the permit is referenced in a combined license application. At that time, the emergency plans would have to be reviewed to confirm

that they are up-to-date and to provide any new information that may materially affect the NRC's earlier determination on emergency preparedness, or correct inaccuracies in the emergency preparedness information approved in the early site permit in support of a reasonable assurance determination, in accordance with § 50.47 and appendix E to part 50. In addition, the NRC agrees with NEI that a "continuous" early site permit update requirement would impose burdens upon the early site permit holder without any commensurate benefit if the early site permit is not subsequently referenced. Accordingly, the Commission has determined that §§ 52.39 and 52.79 should contain an updating requirement to be imposed upon the applicant referencing an early site permit.

A new § 52.39(b) is added to require an applicant for a construction permit, operating license, or combined license, whose application references an early site permit, to update and correct the emergency preparedness information provided under § 52.17(b). In addition, the applicant must discuss whether the new information could materially change the bases for compliance with the applicable NRC requirements. A parallel requirement is included in § 52.79 to ensure that applicants for combined licenses referencing an early site permit will submit the updated emergency preparedness information. Section 52.39(a)(1)(iii) is also added stating that the Commission may modify an early site permit if it determines that a modification is necessary based on updated emergency preparedness information provided in a referencing license application. New information that materially changes the bases for compliance includes information that substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, and information that would constitute a basis for the Commission to modify or impose new terms and conditions on the early site permit related to emergency preparedness in accordance with § 52.39(a)(1). New information that materially changes the NRC's determination of the matters in § 52.17(b), or results in modifications of existing terms and conditions under

§ 52.39(a)(1) will be subject to litigation during the construction permit, operating license, or combined license proceedings in accordance with § 52.39(c).

Not all new information on emergency preparedness will be subject to challenge in a hearing under § 52.39(c). For example, an emergency plan may have to be updated to reflect current telephone numbers, names of governmental officials whose positions and responsibilities are defined in the plan (e.g., the name of the current police chief for a municipality), or current names of hospital facilities. These corrections do not materially change the NRC's previously-stated bases for accepting the early site permit emergency plan, and a hearing contention will not be admitted under § 52.39(c) in a proceeding for a license referencing the early site permit. In contrast, if an emergency plan submitted as part of an early site permit relies upon a bridge to provide the primary path of evacuation, and that bridge no longer exists, the change could materially affect the NRC's previous determination that the emergency plan complied with the Commission's emergency preparedness regulations in effect at the time of the issuance of the early site permit. This type of information might be the basis for a change in the early site permit's terms and conditions related to emergency preparedness under § 52.39(a)(1), as well as the basis for a hearing contention under § 52.39(c), assuming that the requirements in 10 CFR part 2 for admission of a contention are met.

b. Resolution of ITAAC.

Sections 52.99 and 52.103 are revised to incorporate rule language from the design certification regulations in 10 CFR part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of appendix A to part 52). During the preparation of the design certification rules for the ABWR and System 80+ designs, the NRC staff and nuclear industry

representatives agreed on certain requirements for the performance and completion of the inspections, tests, or analyses in ITAAC. In the design certification rulemakings, the NRC codified these ITAAC requirements into Section IX of the regulations. The purpose of the requirement in § 52.99(b) is to clarify that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been met.

Section 52.99(c) requires the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met. The NRC is revising § 52.99(c) in the final rule to clarify that the notification must contain sufficient information to demonstrate that the inspections, tests, or analyses have been successfully completed and that the acceptance criteria have been met. The NRC is adding this clarification to ensure that combined license applicants and holders are aware that the NRC expects the notification of ITAAC completion to contain more information than just a simple statement that the licensee believes the ITAAC has been completed and the acceptance criteria met. The NRC expects the notification to be sufficiently complete and detailed for a reasonable person to understand the bases for the licensee's representation that the inspections, tests, and analyses have been successfully completed and the acceptance criteria have been met. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes "sufficient information" for such a demonstration.

The NRC is also revising § 52.99(c) by adding a new paragraph (c)(2) requiring that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by § 52.99(c)(1) for all ITAAC, then the licensee must notify the NRC that the inspections, tests, or analyses for all uncompleted ITAAC will be successfully completed and all acceptance criteria will be met prior to initial operation (consistent with the

Section 185.b requirement that the Commission, “prior to operation,” find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the inspections, tests, or analyses will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met. Paragraph 52.99(e) has been revised to require that the NRC make available to the public the notifications to be submitted under § 52.99(c)(1) and (c)(2), no later than the *Federal Register* notice of intended operation and opportunity for hearing on ITAAC under § 52.103(a). A conforming change is included in § 2.105(b)(3) to require that the § 52.103(a) notice reference the public availability of the § 52.99(c)(1) and (2) notifications. The NRC is requiring that the paragraph (c)(2) notification be made 225 days before the date scheduled for initial loading of fuel, in order to ensure that the licensee notifications are publicly available through the NRC document room and online through the NRC Web site at the same time that the § 52.103(a) notice is published in the *Federal Register*. The NRC’s goal is to publish that notice 210 days before the date scheduled for fuel loading, but in all cases the § 52.103(a) notice would be published no later than 180 days before the scheduled fuel load, as required by Section 189.a(1)(B).

In Section V of the Supplementary Information of the proposed rule, the NRC requested stakeholder feedback on whether a provision on completion of ITAAC in a set time period prior to fuel load should be added to the final rule. Commenters did not support addition of a requirement on completion of ITAAC in a set time period prior to fuel load and the NRC has not included a provision requiring the completion of all ITAAC by a certain time prior to the licensee’s scheduled fuel load date. Instead, the NRC has decided to modify the concept

slightly by requiring the licensee to submit, with respect to ITAAC which have not yet been completed 225 days before the scheduled date for initial loading of fuel, additional information addressing whether those inspections, tests and analyses will be successfully completed and the acceptance criteria met before initial operation. In the case where the licensee has not completed all ITAAC by 225 days prior to its scheduled fuel load date, the NRC expects the information that the licensee submits related to uncompleted ITAAC to be sufficiently detailed such that the NRC can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. In addition, the NRC is adopting the requirements in paragraphs (c)(1) and (c)(2) to ensure that interested persons will be able to meet the Atomic Energy Act, Section 189.a(1), threshold for requesting a hearing with respect to both completed and as-yet uncompleted ITAAC. The NRC therefore expects that the information submitted by licensees in the § 52.99(c)(2) notification will be sufficiently complete and detailed such that any licensee response to a contention on both completed and uncompleted ITAAC would ordinarily be answered solely by reference to information contained in the notification. Furthermore, the NRC expects that any contentions submitted by prospective intervenors regarding uncompleted ITAAC would focus on the inadequacies of the procedures and analytical methods described by the licensee for completing those ITAAC in the context of the reasonable assurance finding under § 52.103(b)(2). Therefore, the level of detail provided by the licensee should be sufficient to allow a prospective intervenor to form such judgments by reference to that information. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes “sufficient information” to demonstrate that the inspections, tests, or analyses for uncompleted ITAAC will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met.

The NRC notes that, even though it did not include a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date, the NRC will require some period of time to perform its review of the last ITAAC once the licensee submits its notification that the ITAAC has been successfully completed and the acceptance criteria met. In addition, the Commission will require some period of time to perform its review of the staff's conclusions regarding all of the ITAAC and the staff's recommendations regarding the Commission finding under § 52.103(g). Therefore, licensees should structure their construction schedules to take into account these time periods. The NRC intends to develop regulatory guidance on the licensee's completion and NRC verification of ITAAC and will provide estimates of the time it expects to take to verify successful completion of various types of ITAAC. The NRC expects that such guidance, along with frequent communication with licensees during construction, will provide licensees with adequate information to plan initial fuel loading and related activities.

Section 52.99(d) states the options that a licensee will have in the event that it is determined that any of the acceptance criteria in the ITAAC have not been met. The NRC is revising § 52.99(d) in the final rule as a result of a comments made on the proposed rule. Proposed § 52.99(d) stated that, in the event that an activity is subject to an ITAAC derived from a referenced early site permit or standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC, request a variance from the early site permit ITAAC, or request an exemption from the standard design certification ITAAC, as applicable. The language in proposed § 52.99(d) that referred to requesting variances to ESP ITAAC after the COL is issued is inconsistent with rule language in other sections of proposed part 52 (e.g., § 52.39(d)). Therefore, the NRC has adopted the commenters' suggestion to delete references to ESP ITAAC and ESP variances from § 52.99(d).

Paragraph (e)(1) requires the NRC to publish, at appropriate intervals until the last date for submission of requests for hearing under § 52.103(a), notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses. Paragraph (e)(2) provides that the NRC shall make publicly available the licensee notifications under paragraphs (c)(1) and (c)(2). In general, the NRC expects to make the paragraph (c)(1) notifications availability shortly after the NRC has received the notifications and concluded that they are complete and detailed. Furthermore, by the date of the *Federal Register* notice of intended operation and opportunity to request a hearing on whether acceptance criteria have been or will be met (under § 52.103(a)), the NRC will make available the notifications under paragraph (c)(2), and the notifications under paragraph (c)(2) for all ITAAC for which paragraph (c)(1) notifications have not been provided by the licensee.

Finally, § 52.103(h) states that ITAAC do not, by virtue of their inclusion in the combined license, constitute regulatory requirements after the licensee has received authorization to load fuel or for renewal of the license. However, subsequent modifications must comply with the design descriptions in the design control document unless the applicable requirements in the § 52.97 (proposed § 52.98) and Section VIII of the design certification rules have been complied with.

In a letter dated April 3, 2001 (comment 23), NEI requested that the NRC "consider incorporating DCR [Design Certification Rule] general provisions into Subpart C as appropriate." The NRC has added these ITAAC requirements to § 52.99, consistent with NEI's proposal, because it believes that these provisions embody general principles that are applicable to all holders of combined licenses.

The NRC revised § 52.99 in the final rule to delete the requirements in proposed § 52.99(a). Proposed § 52.99(a) required holders of COLs to comply with the provisions of §§ 50.70 and 50.71. Because the language in proposed §§ 50.70 and 50.71 requires COL

holders to comply with their provisions, and because of the applicability provisions in § 52.0(b), this duplicate requirement in § 52.99 is unnecessary.

The NRC is adding new § 52.99(a) in the final rule to require that the licensee submit to the NRC, no later than 1 year after issuance of the combined license, its detailed schedule for completing the inspections, tests, or analyses in the ITAAC. This provision requires the licensee to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under § 52.99(c)(1). In Section V of the Supplementary Information of the 2006 proposed rule, the NRC requested stakeholder feedback on whether such a provision should be added to the final rule. Although some commenters did not believe that a regulatory requirement for submission of a schedule was necessary, the NRC believes it is necessary to ensure the NRC has sufficient information to plan all of the activities necessary for the NRC to support the Commission's finding whether all of the ITAAC have been met prior to the licensee's scheduled date for fuel load.

c. Section 52.73, *Relationship to other subparts.*

Section 52.73 clarifies that a design approval issued under subpart E of part 52 or a manufacturing license under subpart F of part 52 may also be referenced in an application for a combined license filed under 10 CFR part 52. The former § 52.73 only stated that a combined license may reference a standard design certification or an early site permit. The final rule incorporates into new § 52.73(b) the requirement in the current § 52.63(c) in order to clarify that this requirement applies to applicants for a combined license. This provision requires that, before granting a combined license which references a standard design certification,

information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the NRC to make its safety determinations, including the determination that the application is consistent with the certified design. No substantive change is intended by the restatement of this requirement. In a letter dated April 3, 2001 (comments 3 and 3.a), NEI agreed with the proposed change but recommended that the last sentence of § 52.63(c) be deleted and the remaining provision be added to the former § 52.79 rather than the former § 52.73. The NRC agrees with NEI that 10 CFR part 52 should be modified to clarify that the requirement in former § 52.63(c) applied to applicants for a combined license, and that the last sentence be deleted. However, the Commission is adding the remaining provision to the original § 52.73(b), and not to § 52.79, as recommended by NEI.

d. Section 52.75, *Filing of applications.*

Section 52.75 provides requirements for the filing of combined license applications. The NRC has reformatted this section for consistency with the other subparts in 10 CFR part 52 and to replace the references to specific paragraphs within §§ 50.4 and 50.30 with general references to those sections. The specific references are no longer needed because the NRC is adopting conforming changes to §§ 50.4 and 50.30 in this final rule which clarify which provisions are applicable to combined license applications.

e. Section 52.78, *Content of applications; training and qualification of nuclear power plant personnel.*

Section 52.78 has been removed, and the requirements applicable to an applicant for, and holder of, a combined license with respect to the training program are moved to § 50.120, where the requirements currently exist for holders of operating licenses.

f. Section 52.79, *Contents of applications; technical information in final safety analysis report*; and § 52.80, *Contents of application; additional technical information*.

Section 52.79 is reformatted to divide the requirements for the technical contents of a combined license application into two separate provisions. Section 52.79 covers requirements for the contents of the FSAR, and § 52.80 covers requirements for the remainder of the technical content of a combined license application.

Former § 52.79 states that a combined license application must contain the technically relevant information required of applicants for an operating license by 10 CFR 50.34. The reference to 10 CFR 50.34 is removed and replaced with § 52.79(a), which contains all of the relevant requirements from 10 CFR 50.34 that describe what must be included in the FSAR for a combined license application, including requirements that are currently applicable to both construction permit and operating license applications. In addition, requirements from other sections of 10 CFR part 50 (e.g., §§ 50.48 and 50.63) are included. These requirements were issued after the current fleet of operating reactors were licensed and, therefore, were not required contents for these earlier FSARs. In making these modifications, the NRC has attempted to capture all relevant requirements regarding contents of the FSAR for a combined license application.

In addition, § 52.79(a) contains requirements for descriptions of operational programs that need to be included in the FSAR to allow a reasonable assurance finding of acceptability.

This amendment is in support of the Commission's direction to the staff in SRM-SECY-02-0067 dated September 11, 2002, "Inspections, Tests, Analyses, and Acceptance Criteria for Operational Programs (Programmatic ITAAC)," that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application. In this SRM, the Commission stated:

[a]n ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage. The burden is on the applicant to provide the necessary and sufficient programmatic information for approval of the COL without ITAAC.

The Commission clarified its definition of *fully described* in SRM-SECY-04-0032, "Programmatic Information Needed for Approval of a Combined License Application Without Inspections, Tests, Analyses, and Acceptance Criteria," dated May 14, 2004, as follows:

In this context, *fully described* should be understood to mean that the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability. Required programs should always be described at a functional level and at an increased level of detail where implementation choices could materially and negatively affect the program effectiveness and acceptability.

Accordingly, the NRC is adding requirements for descriptions of operational programs. In doing so, the NRC has taken into account NEI's proposal to address SRM-SECY-04-0032 in its letter dated August 31, 2005 (ML052510037). That proposal was reflected in SECY-05-0197 (October 28, 2005, ML052770225), Attachment 1, and approved by the Commission in SRM-SECY-05-0197 dated February 22, 2006 (ML060530316). During the preparation of the final

rule, the NRC discovered that several of the operational programs listed in SECY-05-0197 were not addressed in proposed § 52.79. To ensure the list of requirements for the contents of applications is complete, the NRC is adding several new provisions to address operational programs in the final rule. Specifically, the NRC is adding requirements to § 52.79 for COL applicants to include a description of: (1) the process and effluent monitoring and sampling program required by appendix I to 10 CFR part 50 [§ 52.79(a)(16)(ii)]; (2) a training and qualification plan in accordance with the criteria set forth in appendix B to 10 CFR part 73 [§ 52.79(a)(36)(ii)]; (3) a description of the radiation protection program required by § 20.1101 [§ 52.79(a)(39)]; (4) a description of the fire protection program required by § 50.48 [§ 52.79(a)(40)]; and (5) a description of the fitness-for-duty program required by 10 CFR part 26 [§ 52.79(a)(44)]. During the preparation of the final rule, the NRC also noticed that the proposed rule had not completely implemented the Commission's direction regarding the treatment of operational programs in a COL application inasmuch as requirements to address operational program implementation were not included in proposed § 52.79(a). Therefore, in the final rule, the NRC has added requirements to address the implementation of all operational programs required to be described in a COL application. This is consistent with the Commission's position in SRM-SECY-02-0067 that a combined license applicant is not required to have ITAAC for operational programs if the applicant "fully describes the operational program *and its implementation*" in the combined license application [emphasis added].

In addition, the NRC added a new provision to § 52.79(a) in the final rule to address the application requirements in current § 20.1406. Section 20.1406 requires applicants for a license to describe in their application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. To ensure that § 52.79 contains a complete list of the requirements for the

contents of a COL application, the NRC added paragraph (a)(45) to § 52.79 to require COL applications to include the information required by §20.1406. This is not a new requirement but merely a pointer to an existing requirement to include this information.

Section 52.79(a) requires that emergency plans submitted with a combined license application be included in the FSAR. This modification from the former rule is being made for consistency with § 50.34 which requires that emergency plans be included in the FSAR for operating license applications.

The NRC is adding a new provision in § 52.79(a)(29)(ii) that the applicant submit plans for coping with emergencies, other than the plans required by § 52.79(a)(21).

Paragraph 52.79(a)(21) requires the applicant to submit emergency plans complying with the requirements of § 50.47 and 10 CFR part 50, appendix E. This requirement was drawn from the existing requirement in § 50.34(b)(6)(v) which requires applicants to submit “Plans for coping with emergencies, which shall include the items specified in appendix E.” When this requirement was translated into the associated requirement for combined license applicants, the NRC inadvertently only included a portion of the requirements in § 50.34(b)(6)(v), namely, the requirement in proposed § 52.79(a)(21) to submit emergency plans. The NRC has corrected this omission in the final rule by including the new provision in § 52.79(a)(29)(ii) to include other plans for coping with emergencies. This requirement is meant to capture, for example, emergency operating procedures as discussed in SRP Section 13.5.2.1, “Operating and Emergency Operating Procedures.”

The NRC has moved the requirements contained in proposed § 52.79(a)(23) that addressed a request to conduct activities under § 50.10(e) and added them in a new § 52.80(c). The NRC concluded that it is preferable to include both the list of proposed § 50.10(e) activities and the redress plan as separate documents in the application, outside of both the site safety analysis report and the environmental report. The NRC’s conclusion is based on the fact that

the requirements in § 50.10(e) address both safety and environmental issues. Additional changes were made to §§ 51.50, 52.17, and 52.80 to implement this concept.

The NRC also revised § 52.79(a)(41) to require that the applicant evaluate its facility against both the NRC's review guidance in the standard review plan (SRP) and the regulatory guide on "Combined License Applications for Nuclear Power Plants" (currently DG-1145). By referring to both the review guidance and application guidance, the NRC will ensure that future applications for combined licenses (COLs) will conform with the latest guidance for application format and content, as well as the review criteria. The NRC expects that the use of DG-1145 and the SRP will facilitate the preparation and review of future COL applications. For COL applicants that reference the same design certification rule and adopt a design-centered approach in preparing their COL applications, the NRC expects that the "reference application" will fully conform with this requirement and any follow-on applications will not need to provide the evaluations for the application information that is identical to the reference application.

The NRC has moved the requirement that COL applicants submit a plant-specific PRA that was in proposed § 52.80(a) to a new § 52.79(a)(46) in the final rule based on public comments. In addition, the NRC has revised the provision to require the applicants submit a description of their PRA and its results in their COL FSAR. The NRC agrees with some commenters who believed that applicants should not be required to submit their complete plant-specific PRA and that, instead, applicants should only be required to provide a summary description of the PRA and its results in their FSAR with the understanding that the complete PRA (*e.g.*, codes) would be available for NRC inspection at the applicant's offices, if needed. The NRC expects that, generally, the information that it needs to perform its review of the COL application from a PRA perspective is that information that will be contained in applicants' FSAR Chapter 19. The NRC believes that COL application guidance that the NRC is developing is consistent with the industry comment in that the staff does not expect the complete PRA to be

included in the COL applicant's FSAR. Instead, the guidance is oriented towards the qualitative description of the PRA results, insights, uses, etc.

Section 52.79(b) describes the variant on the requirements in § 52.79(a) for a combined license application that references an early site permit. Former § 52.79(a) did not explicitly require the application to address whether the terms and conditions specified in the early site permit under § 52.24 have been or will be met by the combined license holder, although this is implicit by the inclusion of any terms and conditions in the early site permit. To remove any ambiguity in this matter, § 52.79(b)(3) requires that the FSAR demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the combined license. The NRC is revising § 52.79(b)(3) in the final rule based on public comments to add an exclusion for terms and conditions imposed under § 50.36(b) because such environmental conditions should be addressed in the environmental report and not in the final safety analysis report. In addition, the Commission is revising this paragraph to add a provision that any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license must be set forth as terms or conditions of the combined license. This provision is needed to address terms or conditions of the early site permit that are related to activities that will not take place until after issuance of the combined license, such as construction activities. A similar change is being made to §§ 52.79(d)(3) and (e)(3) for referenced design certifications and manufacturing licenses.

The NRC is making a revision to the language in proposed § 52.79(b)(1) in the final rule. Proposed § 52.79(b)(1) stated that the FSAR for a combined license application referencing an early site permit need not contain information or analyses submitted to the NRC in connection with the early site permit. This rule language led to a great deal of discussion both within the NRC and in public meetings on combined license application guidance as to what the NRC expected to see in a combined license application that referenced an early site permit. The

NRC has concluded that the FSARs in these combined licenses applications must either include or incorporate by reference the SSAR for the early site permit. The SSAR must be included or incorporated into the COL FSAR to ensure that matters addressed in the SSAR legally become part of the FSAR upon issuance of the COL. This will also ensure that the information in the SSAR is subject to control under § 50.59 after issuance of the COL. For these reasons, the NRC is modifying the language in § 52.79(b)(1) to state that the final safety analysis report need not contain information or analyses submitted to the NRC in connection with the early site permit. However, the final safety analysis report must either include or incorporate by reference the early site permit site safety analysis report. With this modification, the NRC intends to convey that the combined license applicant referencing the early site permit does not need to resubmit, for NRC review, information or analyses that were already reviewed and resolved in the early site permit proceeding (such as information provided in responses to NRC requests for additional information). At the same time, the NRC's goal is to provide COL applicants clear guidance as to what the combined license application must contain to be considered complete. For similar reasons, the NRC is also modifying the language in proposed §§ 52.79(c)(1), (d)(1), and (e)(1) to include the provision that the FSAR in the COL application must either include or incorporate by reference the FSAR for the design approval, design certification, or manufacturing license that it is referencing. Note that each of the existing design certification rules covered in appendices A-D of part 52 prohibit the use of incorporation by reference in COL FSARs that reference them. At the time those rules were issued, the NRC was concerned that the staff would not have easy access to the final version of the design certification FSAR (*i.e.*, DCD) if it were not included in the COL application. The NRC will continue to put restrictions in individual design certification rules (and possibly in early site permits, design approvals, or manufacturing licenses) if it does not have confidence that the

safety analysis reports can be easily accessed by the staff if they are incorporated by reference in COL applications.

Section 52.79(c) describes the requirements for combined license applications that reference a standard design approval. Previously, no guidance was provided regarding a combined license application that referenced a standard design approval. The requirements in § 52.79(c) are essentially the same as those for a combined license application that references a standard design certification in § 52.79(d).

Section 52.79(d) describes the requirements for combined license applications that reference a standard design certification. Section 52.79(d) states that the FSAR for a combined license application referencing a standard design certification need not contain information or analyses submitted to the NRC in connection with the design certification. However, the final safety analysis report must either include or incorporate by reference the standard design certification final safety analysis report (see discussion above) and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design certification. In addition, paragraph (d) requires that the plant-specific PRA information must use the PRA information for the design certification and must be updated to account for site-specific design information and any design changes or departures. In the case where a COL application is referencing a design certification, the NRC only expects the design changes and differences in the modeling (or its uses) pertinent to the PRA information to be addressed to meet the submittal requirement of § 52.79(d)(1). Section 52.79(d) also requires that the FSAR demonstrate that the interface requirements established for the design under § 52.47 have been met and that all requirements and restrictions that may have been set forth in the referenced design certification rule be satisfied by the date of issuance of the combined license.

Section 52.79(e) describes the requirements for a combined license application that references a manufactured reactor. Previously, no guidance was provided regarding a combined license application that referenced a manufactured reactor. These requirements are similar to those for the content of an FSAR for a combined license referencing a design certification. Specifically, § 52.79(e) states that the FSAR need not contain information or analyses submitted to the NRC in connection with the manufacturing license. However, the final safety analysis report must either include or incorporate by reference the manufacturing license final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the manufacturing license. This language was slightly different in the proposed rule and has been corrected in the final rule to be consistent with § 52.79(d). In addition, § 52.79(e) requires that the plant-specific PRA information must use the PRA information for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures. Section 52.79(e) also requires that the FSAR demonstrate that the interface requirements established for the design have been met and that all terms and conditions that have been included in the manufacturing license be satisfied by the date of issuance of the combined license.

Section 52.80 is added to cover the required technical contents of a combined license application that are not contained in the FSAR. These application contents include the ITAAC, the environmental report, and the request to perform activities under § 50.10(e) with the associated redress plan. This last item was moved to § 52.80(c) in the final rule from its location in § 52.79(a)(23) in the proposed rule. The NRC concluded that it is preferable to include both the list of proposed activities and the redress plan as separate documents in the application, outside of both the site safety analysis report and the environmental report. The NRC's conclusion is based on the fact that the requirements in § 50.10(e) address both safety

and environmental issues. Additional changes were made to §§ 51.50 and 52.17 to implement this concept.

g. Section 52.81, *Standards for review of applications.*

10 CFR parts 54 and 140 are added to the list of standards that the NRC will use to review combined license applications. Part 54 addresses applications for renewal of combined licenses and part 140 includes the requirements applicable to nuclear reactor licensees with respect to financial protection and Indemnity Agreements to implement Section 170 of the AEA, commonly referred to as the Price-Anderson Act.

h. Section 52.83, *Finality of referenced NRC approvals.*

The former § 52.83, *Applicability of part 50 provisions*, is removed and replaced by a new section addressing the finality of NRC approvals which are referenced in a combined license application. Former § 52.83 provides that, unless otherwise specifically provided for in subpart C to part 52, all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits for nuclear power reactors also apply to holders of combined licenses. Similarly, § 52.83 provides that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses issued under this subpart, once the Commission has made the findings required under § 52.99. The NRC believes that the former § 52.83 is not necessary because this proposed rulemaking will provide conforming changes throughout 10 CFR part 50 (as well as all other parts in Title 10 Chapter 1) to identify which requirements are applicable to combined license applicants and holders.

Former § 52.83 also provides provisions that address the duration of a combined license and these provisions would be moved to proposed § 52.104, *Duration of combined license*.

The new § 52.83 states that, if an application for a combined license references an early site permit, design certification rule, standard design approval, or manufacturing license, the scope and nature of matters resolved for the application and any combined license issued are governed by the relevant provisions addressing finality, including §§ 52.39, 52.63, 52.98, 52.145, and 52.171. This provision clarifies the relationship between a combined license application and any other license or regulatory approval that an applicant may reference in the combined license application as far as issue resolution is concerned.

i. Section 52.89, *Environmental review*.

Section 52.89 is removed and reserved for future use. Former § 52.89 required that, if a combined license application references an early site permit or a certified standard design, the environmental review must focus on whether the design of the facility falls within the parameters specified in the early site permit and any other significant environmental issue not considered in any previous proceeding on the site or the design. Former § 52.89 further stated that, if the application does not reference an early site permit or a certified standard design, the environmental review procedures set out in 10 CFR part 51 must be followed, including the issuance of a final environmental impact statement, but excluding the issuance of a supplement under § 51.95(a). This provision is removed because the requirements for compliance with NEPA are now captured in § 52.79(a) and in the revisions to part 51.

j. Section 52.91, *Authorization to conduct site activities*.

Section 52.91(a)(2) formerly provided requirements for a combined license application that does not reference an early site permit, but that contains a site redress plan and states that the applicant may not perform the site preparation activities allowed by 10 CFR 50.10(e)(1) without first submitting a site redress plan in accordance with § 52.79(a)(3), and obtaining the separate authorization required by 10 CFR 50.10(e)(1). This provision further states that authorization must be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by 10 CFR 50.10(e)(2), and has determined that the site redress plan meets the criteria in § 52.17(c). This provision is amended to state that authorization *may* [emphasis added] be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by 10 CFR 50.10(e)(2), and has determined that the site redress plan meets the criteria in § 52.17(c). This amendment is consistent with § 52.91(a)(3), which states that authorization to conduct the activities described in 10 CFR 50.10(e)(3)(i) may be granted only after the presiding officer in the combined license proceeding makes the additional finding required by 10 CFR 50.10(e)(3)(ii). The NRC believes that *may* is the proper term to use in both of these provisions, to reflect the NRC's residual authority to decline to authorize the ESP holder to conduct § 50.10(e)(3)(i) activities, even if the NRC's regulations are met.

k. Section 52.93, *Exemptions and variances*.

Paragraph (a) of § 52.93, which includes a discussion of the requirements regarding requests for an exemption from any part of a referenced design certification, is revised to state that the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced design certification rule, or with § 52.63 if there are

no applicable exemption provisions in the referenced design certification rule. This provision formerly referred to compliance with § 50.12(a). The NRC is revising paragraph (b) of this section in the final rule to include an allowance for applicants to request a variance from the early site permit SSAR. The allowance for requesting variances to the SSAR was inadvertently omitted in the proposed rule. Because the majority of the early site permit information that a combined license applicant will be referencing will be the information in the SSAR, it is logical that the allowance to request variances be extended to the information in the SSAR given that the NRC is allowing variances to the permit itself. In the final rule, the NRC is also adding a provision to paragraph (b) of this section that precludes the NRC from issuing a variance once a construction permit, operating license, or combined license referencing the early site permit is issued; any changes that would otherwise require a variance should instead be treated as an amendment to the construction permit or combined license.

Section 52.93 is also revised in the final rule to add a discussion of requests for departures from a referenced nuclear power reactor manufactured under a manufacturing license in new paragraph (c) of this section. This provision was inadvertently omitted in the proposed rule, although similar provisions were addressed in the proposed rule in §§ 52.98 and 52.171. However, the proposed rule incorrectly used the term “variance” to describe an application-specific change to a reactor manufactured under a manufacturing license. The NRC has corrected these provisions in the final rule to use the term “departure” for such changes, consistent with the terminology used for changes to a referenced design certification. New paragraph (c) of this section is consistent with these other sections and states that an applicant for a combined license who has filed an application referencing a nuclear power reactor manufactured under a manufacturing license may include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The NRC may grant a request only if it

determines that the departure will comply with the requirements of 10 CFR 52.7, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The criteria for granting the departure is the exemption criterion in § 52.7; however, the departure itself is *not* considered an exemption (unless, of course, the departure also involves a non-compliance with an underlying Commission regulatory requirement in 10 CFR Chapter 1). Thus, the Commission will not approve a departure unless the Commission finds, in addition to the routine exemption criteria in § 52.7, that special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. These limitations are intended to maintain the standardization of manufactured reactors in operation to the extent practicable. The licensee may not depart from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor through the provisions of § 50.59.

Finally, the provision contained in paragraph (c) of this section in the 2006 proposed rule (and in paragraph (b) in the former rule) has been moved to paragraph (d) of this section in the final rule. This provision states that issuance of a variance under paragraph (b) or a departure under paragraph (c) is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

I. Section 52.97, *Issuance of combined licenses.*

The NRC has modified § 52.97 to be more consistent with the parallel provision in § 50.50, *Issuance of licenses and construction permits*, by including requirements that, after conducting a hearing and receiving the report submitted by the ACRS, the NRC finds that there is reasonable assurance that the applicant is technically and financially qualified to engage in

activities authorized; and that issuance of the license will not be inimical to the common defense and security or to the health and safety of the public. Section 52.97(c) is added, consistent with § 50.50, which states that a combined license shall contain conditions and limitations, including technical specifications, as the NRC deems necessary and appropriate. Former § 52.97(b)(2) is moved to new § 52.98 because the issues addressed in this section are issues associated with finality of combined license provisions.

m. Section 52.98, *Finality of combined licenses; information requests.*

Section 52.98, which addresses the finality associated with the issuance of combined licenses, is added to subpart C of part 52, consistent with the other subparts in 10 CFR part 52. Section 52.98(a) states that, after issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of §§ 52.103 or 50.109, as applicable.

Section 52.98 includes provisions to clarify the applicability of the change processes in 10 CFR part 50 and Section VIII of the design certification rules in 10 CFR part 52 to a combined license. Section 52.98(b) states that the change processes in 10 CFR part 50 apply to a combined license that does not reference a design certification rule or a reactor manufactured under a manufacturing license. Section 52.98(c) states that the change processes in Section VIII of the design certification rules apply to changes within the scope of the referenced certified design. However, if the proposed change affects the design information that is outside of the scope of the design certification rule, the part 50 change

processes apply unless the change also affects the design certification information. For that situation, both change processes may apply.

Section 52.98(d) is added to address changes to a combined license that references a reactor manufactured under a manufacturing license. Section 52.98(d)(1) states that, if the combined license references a reactor manufactured under a subpart F manufacturing license, then changes to or departures from information within the scope of the manufactured reactor's design are subject to the change processes in § 52.171. Note that the proposed rule incorrectly used the term "variance" to describe an application-specific change to a reactor manufactured under a manufacturing license. The NRC has corrected this provision in the final rule to use the term "departure" for such changes, consistent with the terminology used for changes to a referenced design certification. Section 52.98(d)(2) states that changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in 10 CFR part 50 (e.g., §§ 50.54, 50.59, and 50.90). The NRC made all of these requirements to clarify, in one location, the finality provisions applicable to all portions of a combined license.

Finally, the NRC has added a new paragraph (g) to the "finality" section in each subpart of part 52, including § 52.98, entitled "Information requests," which delineates the restrictions on the NRC for information requests to the holder of the combined license. This provision is analogous to the former provision on information requests in paragraph 8 of appendix O to parts 50 and 52, and is based upon the language of § 50.54(f). For combined licenses, this proposed provision is in § 52.98(g), and requires the NRC to evaluate each information request of the holder of a combined license to determine that the burden imposed by the information request is justified in light of the potential safety significance of the issue to be addressed in the information request. The only exception is for information requests seeking to verify compliance with the current licensing basis of the facility. If the request is from the NRC staff, the request will first have to be approved by the EDO or his or her designee.

n. Section 52.103, *Operation under a combined license.*

Section 52.103(g) formerly required the NRC to find that the acceptance criteria in the combined license are met before operation of the facility, but did not refer to loading of fuel. However, § 52.103(f) stated that fuel loading and operation under the combined license will not be affected by the granting of a petition to modify the terms and conditions of the combined license unless a Commission order is made immediately effective. In the proposed rule, this section was amended to require the NRC to find that the acceptance criteria in the combined license are met before fuel load and operation of the facility. The NRC has decided not to adopt the proposed rule language which would have precluded loading of fuel into the reactor until acceptance criteria has been met. The NRC believes that the rule should reflect, as closely as possible, the statutory requirement in Section 185.b of the AEA. The NRC has historically viewed “operation” as including loading of fuel into the reactor, however it is not necessary to change the language of § 52.103(g) to continue the historical practice. The NRC believes that this is the common interpretation of § 52.103(g).

o. Section 52.104, *Duration of combined license*; § 52.105, *Transfer of combined license*; § 52.107, *Application for renewal*; § 52.109, *Continuation of combined license*; and § 52.110, *Termination of license.*

Five new provisions are added to subpart C of part 52 for consistency with the other subparts in 10 CFR part 52 and to parallel requirements in 10 CFR part 50 for operating licenses. Section 52.104, addresses the duration of a combined license and contains requirements that formerly existed in § 52.83. In addition, the Commission has amended these

requirements to indicate that, where the Commission has allowed operation under a combined license during an interim period under § 52.103(c), the period of operation is not to exceed 40 years from the date allowing operation during the interim period.

Section 52.105 provides requirements for the transfer of a combined license that refer the applicant to § 50.80. Section 52.107 provides a reference to 10 CFR part 54 for the renewal of a combined license.

Section 52.109 provides provisions for the continuation of a combined license and § 52.110 would provide requirements for the termination of a combined license. Formerly, part 52 did not address decommissioning of combined licenses (reactors that are manufactured under a part 52 manufacturing license do not raise decommissioning concerns until they are emplaced at a site, inasmuch as a manufacturing license does not permit loading of fuel or operation) and the termination of the combined license. By contrast, §§ 50.51 and 50.82 address the permanent shutdown of a nuclear power plant, its decommissioning, and the termination of the part 50 operating license. There are two possible ways of addressing this omission: §§ 50.51 and 50.82 could be modified to reference combined licenses under part 52, or the provisions analogous to these sections could be added to part 52. The NRC believes that the second alternative is the best approach. The combined license holder's responsibilities upon expiration of its license is more a matter of regulatory authority and therefore is best placed in part 52. While the question is closer with respect to decommissioning, the NRC believes that most users would likely turn to part 52 rather than part 50 to determine the requirements for decommissioning, inasmuch as decommissioning involves questions of both procedure and technical requirements.

9. Subpart D, Reserved.

10. Subpart E, *Standard Design Approvals (§§ 52.131 through 52.147).*

The former appendix O to part 52 set forth the requirements for NRC staff approval of a standard design for a nuclear plant or a major portion of a nuclear plant. This licensing process was first adopted by the NRC in 1975 and has been used many times, including issuance of four final design approvals (FDAs) under appendix O to part 52 from 1994 through 2004. These FDAs were issued during previous design certification reviews when FDAs were a prerequisite to certification of a standard plant design (see SOC discussion on 10 CFR 52.43).

When the NRC adopted part 52 in 1989, the Commission did not re-examine the regulatory scheme for standard design approvals to determine if the bases for adopting part 52 and the licensing processes codified in part 52 would also be an impetus for reorganizing the design approval process. However, the Commission did undertake a re-examination of appendix O to part 52 in the 2003 proposed rule and proposed certain changes. In view of the substantial reorganization and rewriting of part 52 in this rulemaking, the Commission gave further consideration to the licensing process in appendix O to part 52 and has made additional changes to enhance the regulatory effectiveness and efficiency of that licensing process.

The Commission continues to believe that the best approach for obtaining early resolution of design issues is through the design certification process in subpart B of part 52. Design certification will provide greater finality and standardization than the design approval process. Consequently, the Commission favors use of the design certification process, which suggests that the design approval process could be eliminated. However, given the frequent use of appendix O to part 52 in the past, the Commission has decided to retain this process and to reorganize and reformat the design approval process to be consistent with other subparts.

The design approval process, formerly located in appendix O to part 52, has been moved to subpart E of part 52 and reformatted to be consistent with other subparts. A new § 52.133 was created to describe the relationship of the design approval process with other subparts. An FDA may be referenced in an application for a construction permit or operating license under part 50 or a design certification, combined license, or manufacturing license under part 52.

The filing requirements for design approvals are consistent with other subparts of part 52. The applicants may still request approval of either the entire facility or major portions thereof, but the applications are limited to final design information. There are several reasons for this change. First, the Commission's recent experience with FDAs and design certifications demonstrates that nuclear plant designers are technically capable of developing essentially complete and final design information for NRC review and approval. Furthermore, the economic incentives with respect to design certification also apply to final design approvals. In addition, approval of final design information removes the unpredictability of issuing a construction permit that references only preliminary design information and initiating construction while the final design information is being developed. Approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the construction of the plant, which will greatly enhance regulatory stability and predictability.

The Commission has decided that the contents of applications for design approvals should contain essentially the same technical information that is required of design certification applications (e.g., demonstration of compliance with technically relevant Three Mile Island requirements, proposed technical resolutions of unresolved safety issues and medium- and high-priority generic safety issues, and design-specific probabilistic risk assessment information).

Regarding applications for a major portion of the standard plant design, such as the nuclear steam supply system, the application only needs to contain the information required for the contents of applications that are applicable to the major portion of the plant for which NRC staff approval is requested.

The requirements for contents of applications for design approvals (§ 52.137) were renumbered to be consistent with the numbering of requirements in § 52.47. Also, many of the public comments on contents of applications for design certification apply to the requirements for design approvals (see the SOC of this document for the discussion for § 52.47). Some commenters recommended that the requirement for coping with emergencies [§ 52.137(a)(11)] be deleted because applicants for design approvals will not be responsible for certain emergency planning design features. The Commission disagrees with this comment. First of all, this requirement was taken from the original appendix O of part 52, paragraph 3, and it applies to design features for coping with emergencies in the operation of the reactor, not solely for emergency planning.

A new § 52.139, which specifies the standards that will be used to review applications for design approvals and new §§ 52.145 and 52.147, which specify the finality and duration of design approvals was added to be consistent with other subparts. In a letter dated November 13, 2001, NEI commented that “Industry recommends FDAs be valid for 15 years.” The Commission agrees with NEI’s recommendation and has decided that the duration of standard design approvals should correspond to the duration of design certifications, inasmuch as both design approvals and design certifications constitute approvals of nuclear power plant designs, and the period of effectiveness of the approval from a technical standpoint is not a function of whether the approval is granted by the NRC staff or the Commission. Some commenters recommended that § 52.147 be rewritten to provide for renewals of standard design approvals. The Commission disagrees with this comment. The original appendix O to

part 52 did not contain a process for renewing design approvals and most of the design approvals issued under appendix O to part 52 were for a 5-year duration. In this rulemaking, the Commission has tripled the duration for a design approval and believes that renewals will not be necessary. Also, as stated before, the Commission favors the use of the design certification process, which includes a process for renewals.

11. Subpart F, Manufacturing Licenses.

The following discussion explains the requirements in subpart F of part 52 generically, and covers §§ 52.151, 52.153, 52.155, 52.156, 52.157, 52.159, 52.161, 52.163, 52.165, 52.167, 52.169, 52.171, 52.173, 52.175, 52.177, 52.179, and 52.181.

Former appendix M of parts 50 and 52 set forth the NRC's requirements governing manufacturing licenses. Appendix M, which was first adopted by the NRC in 1973 as an appendix to part 50, provided for issuance of a license authorizing the manufacture of a nuclear power reactor to be incorporated into a nuclear power plant under a construction permit and operated under an operating license at a different location from the place of manufacture. Under the licensing regime in former appendix M, the NRC did not approve a final reactor design to be manufactured as part of the issuance of the manufacturing license. Rather, analogous to the two-step construction permit/operating license process, the NRC would issue a manufacturing license based upon the review and approval of a preliminary design equivalent to that provided in a construction permit application. Upon issuance of the manufacturing license, manufacturing of the reactor can commence, although the NRC must approve the final design of the manufactured reactor by license amendment before the manufactured reactor may be transported from the place of manufacture to the site where it is to operated.

When the NRC adopted part 52 in 1989, it added appendix M to part 52. However, the NRC did not re-examine the regulatory scheme for manufacturing licenses in order to determine if the bases for adopting part 52 would also be an impetus for changing the regulatory scheme for manufacturing licenses. Nor did the NRC undertake such a re-examination as part of the process leading to the 2003 proposed rule. However, the NRC has reconsidered the efficacy of the manufacturing license process in former appendix M to part 52, and has decided to adopt substantial changes to those requirements in order to enhance regulatory effectiveness and efficiency. These new requirements are contained in a new subpart F to part 52.

The most important shift in the manufacturing license concept in subpart F is that a final reactor design, equivalent to that required for a standard design certification under part 52 or an operating license under part 50, must be submitted and approved before issuance of a manufacturing license. There are several reasons for this shift. First, the Commission's experience with standard design certifications demonstrates that nuclear power plant designers are technically capable of developing a complete reactor design for Commission review. Furthermore, the economic incentives and limitations with respect to approval of a standard reactor design certification also apply to the approval of a design of a manufactured reactor. Indeed, one could argue that the holder of a manufacturing license may structure the commercial transaction to reduce the economic risk associated with the application for a manufacturing license for a final reactor design, as compared to the economic risk associated with a standard design certification. Second, approval of a final reactor design removes the former awkward regulatory process of issuing a manufacturing license, and subsequently amending the license when a final design is submitted. Approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the actual manufacture of the reactor, which will greatly enhance

regulatory stability and predictability. Finally, Commission approval of standardized manufacturing processes, coupled together with the potential for a stable workforce and the application of manufacturing process feedback, has great opportunities for maintaining and even improving the quality and consistency of manufacture, as compared to the traditional method of constructing reactors onsite by a variety of contractors and subcontractors.

The technical information required to be included in an application for a manufacturing license, as set forth in §§ 52.157 and 52.158, reflects both the expansion of the scope of approval to include the final design of the reactor to be manufactured, as well as lessons learned with respect to the NRC's review of early site permits. Section 52.157, which sets forth the technical information to be submitted in support of the design of a reactor, is derived from the existing requirements in current part 52, subparts B and C, governing the technical information to be submitted in support of an application for a standard design certification and combined license. In addition, § 52.157 requires that the application address the provisions with respect to the demonstration by test, analysis, experience, or a combination thereof, of simplified, inherent, passive, or other innovative means to accomplish safety functions, or the results of testing of a prototype plant, as set forth in revisions to § 50.43. As discussed separately with respect to § 50.43, these testing and prototype requirements incorporated into § 50.43 were derived from the former requirements in § 52.47(b).

Information which must be submitted as part of an application, but is not typically considered part of a final safety analysis report, is identified in § 52.158. This includes proposed ITAAC to be used by the licensee who will construct and operate a nuclear power plant at its site using the manufactured reactor and an environmental report for the manufactured reactor. Note that, in the final rule, the NRC has moved proposed § 52.158(a) to a new § 52.157(f)(31) which requires that manufacturing license applicants submit a description of the design-specific PRA and its results in the FSAR. The NRC agrees with some

commenters that applicants should not be required to submit their complete design-specific PRA and that, instead, applicants should only be required to provide a summary description of the PRA and its results in their FSAR with the understanding that the complete PRA (e.g., codes) would be available for NRC inspection at the applicant's offices, if needed. The NRC expects that, generally, the information that it needs to perform its review of the manufacturing license application from a PRA perspective is that information that will be contained in applicants' FSAR Chapter 19.

The environmental report must address SAMDAs, similar to standard design certifications, because the design approval stage is usually the most cost-effective opportunity for incorporating design features for addressing severe accidents. The NRC notes that the environmental report need not address environmental impacts associated with the actual manufacture of the reactor at any manufacturing location, inasmuch as a manufacturing license does not represent NRC approval of any specific location, facility, or appurtenance for manufacturing. Rather, the NRC is approving a reactor design for manufacture and the ITAAC for verifying that it has been acceptably manufactured and integrated into a nuclear power facility so that it can be safely operated in accordance with the approved manufactured reactor design, the NRC's regulations, and the requirements of the AEA. These determinations were reflected in proposed §§ 52.158(c)(1), 51.54, and 51.75(c)(3). However, in the final rule, the Commission has removed from §§ 52.158(c)(1) and (2) the rule language addressing the content of the environmental report, and integrated that language into §§ 51.54 and 51.75(c)(3). Section 52.158(c)(2) has been revised in the final rule to address the scope of the environmental report if the manufacturing license application has referenced a standard design certification.

Section 52.163 of the March 2006 proposed rule would have required that the NRC conduct a "mandatory" hearing in connection with the initial issuance of a manufacturing

license, even though the AEA does not require a mandatory hearing for issuance of manufacturing licenses. For the reasons set forth in the NRC's response to Commission Question 2, and the discussion on §§ 2.104 and 2.105, the NRC has decided not to require a "mandatory" hearing for initial issuance of a manufacturing license, and § 52.163 is revised in the final rule to refer to a publication of a notice of proposed action under § 2.105, rather than a notice of hearing under § 2.104.

In light of the NRC's review and approval of a final design as part of issuance of a manufacturing license, the final rule provides a greater degree of finality to a manufacturing license as compared with a standard design certification. Under § 52.171(a)(1), the same degree of issue finality accorded to the "certified design" applies throughout the term of the manufacturing license. Under this provision, the NRC may not impose any change or modification to the approved design (including site parameters, or design characteristics) for the manufacturing license unless the NRC determines that the change or modification is necessary either for adequate protection or for compliance with requirements applicable and in effect at the time the manufacturing license was issued. Similarly, the manufacturing license holder may not make changes to the design under the provisions of 10 CFR 50.59. Any change to the design will require a license amendment. The Commission regards this as similar to the level of change control imposed on designs which are the subject of a standard design certification. The Commission is imposing this stringent level of change control because one of the key reasons for licensing manufactured reactors is to enhance standardization—one of the original objectives of the 1989 part 52 rulemaking. Unlike design certification, which is an approval of a "paper design," the NRC's proposed concept of a manufacturing license is pre-approval of the procurement, manufacturing, and quality assurance processes that translates the approved reactor design into a manufactured assembly in a controlled environment, with the capability to optimize techniques and procedures based upon feedback. Some of these advantages may be

lost if each “manufactured” reactor were treated as a “one-off” custom product. Imposing the discipline of a license amendment process should ensure that a profusion of changes are not made to the approved design at random intervals. The Commission disagrees with commenters on the proposed rule that the design of a manufactured reactor should be subject to less-stringent change provisions than a standard design certification. The commenters have not demonstrated that there are special or unique aspects of manufacturing, as compared with the construction of a nuclear power plant based upon a referenced standard design certification, that would weigh against maintaining the high degree of *design* standardization achieved by design certification. One commenter correctly noted that changes in such manufacturing matters as procurement, manufacturing processes, or quality assurance are *not* subject to the proposed § 52.171(b)(1) change restriction, because these matters do not constitute changes to the approved design of the reactor to be manufactured. These changes would be governed by the applicable change process and restrictions already established in the Commission’s regulations such as § 50.59, and § 50.54(a), and may not require license amendments.

The only relevant rationale provided by the commenters is that obsolescence of components and component manufacturers’ changes would necessitate minor changes to the reactor design over a 15-year period. Although the Commission acknowledges the likelihood of these factors, the NRC staff does not see any reason why these factors are more likely to affect the design of a manufactured reactor as compared with the design approved in a design certification. It is not clear why a change in component sourcing would necessarily result in a “design change” requiring an amendment to the manufacturing license. Finally, the Commission notes that the proposed rule does not mandate “zero changes in a reactor design.” As specifically stated in the SOC of the March 13, 2006 (71 FR 12801), proposed rule (second

column), proposed § 52.171(b)(1) would allow the manufacturer to make changes to the approved design to be manufactured, albeit by license amendment.

The final rule provides that the term of a manufacturing license to be for no less than 5, or more than 15 years from the date of issuance. The Commission established the 15-year maximum term to be consistent with the maximum term for a standard design certification. The 5-year minimum term was established by the Commission to encourage the use of a manufacturing license for the manufacture of more than one nuclear power reactor. The language of § 52.171 has been corrected in the final rule by replacing the reference in paragraph (b)(1) to § 50.12 with a reference to § 52.7, and replacing the term, “exemption,” in paragraph (b)(2) with “departure.”

In proposed § 52.167(b)(3), the Commission included a provision which would have required the manufacturing license to specify the number of reactors authorized to be manufactured under the manufacturing license. Upon further consideration in response to a comment on the proposed rule, the Commission has decided that there is no valid regulatory basis for including this provision, and it may in fact serve as a disincentive for the manufacturer to improve the efficiency and productivity of the manufacturing process. Accordingly, this provision is not included in the final rule.

Under § 52.177(c), the holder of a manufacturing license may not commence manufacturing of a reactor less than 3 years before the expiration date, but may continue the manufacturing of a reactor whose manufacture commenced before the 3-year deadline up to license expiration. If, however, an application for renewal is timely-filed with the NRC, manufacturing of a reactor whose manufacture commenced before the 3-year deadline may continue until the time that the NRC completes action on the renewal application in accordance with the Timely Renewal Doctrine of the Administrative Procedure Act (APA). The Commission believes that the timely renewal period should be based upon the time reasonably needed by

the agency to complete action on a renewal application, so that an applicant's reliance upon timely renewal is the rare exception rather than the rule. The NRC selected the 3-year deadline as a reasonable period for completing the manufacture of a nuclear power reactor, based in large part upon public statements by various reactor vendors that they have set goals for constructing complete nuclear power plants onsite within 3 years. It seems reasonable, therefore, that a manufactured reactor, built in a controlled environment using industrial manufacturing processes, would be able to be manufactured in the same 3-year period as the construction of an entire facility onsite. Paragraph (b) is corrected in the final rule by removing the phrase, "that the Commission may impose," in order to avoid the possible misinterpretation that the Commission could choose not to impose new adequate protection requirements identified by the Commission. In addition, paragraph (b)(2) is corrected by removing the reference to "site permit" and substituting the term, "manufacturing license."

The final rule does not require that the manufacturing license specify an earliest and latest date for completion of manufacture of any individual reactor. Section 185 of the AEA directs that "[t]he construction permit shall state the earliest and latest date for completion of the construction or modification." Inasmuch as a manufacturing license is not a construction permit, there does not appear to be any legal need for the manufacturing license to specify the earliest and latest date of completion of manufacture. The language of this section has been corrected in the final rule to make clear that the duration of the renewed manufacturing license consists of the renewed term plus any period remaining on the superseded license (analogous to the determination of the duration of a renewed operating license under part 54).

12. Subpart G of part 52 [Reserved].

13. Subpart H of part 52—Enforcement.

This subpart contains two provisions, § 52.301 and § 52.303, which are comparable to former § 52.111 and § 52.113, and are analogous to provisions contained in other parts of 10 CFR Chapter 1 imposing requirements on regulated entities. Section 52.301 reiterates, and provides notice to licensees and applicants under part 52 of the Commission's authority to obtain injunctions or other court orders for the enumerated violations. Section 52.113 provides notice to all persons and entities subject to part 52 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 52. The regulations listed in paragraph (b), for which criminal sanctions do not apply, have been updated to reflect the final part 52 rulemaking. Section 52.99 was erroneously listed in paragraph (b) in the proposed rule. Because that regulation contains substantive requirements which are promulgated under Section 161.b., i, and o of the AEA, it has been removed from the list of regulations in paragraph (b).

14. Appendices A, B, and C to Part 52—Design Certifications for ABWR, System 80+, and AP600.

The NRC amended paragraphs VI.B.4, 5, and 6 of the three design certification rules in appendices A, B, and C to part 52 for the U.S. ABWR, System 80+, and AP600 designs, respectively, by substituting the phrase "but only for that *plant*" for the erroneous phrase "but only for that *proceeding*" (emphasis added). The new phrase correctly characterizes the scope of issue resolution in three situations. Paragraph VI.B.4 describes how issues associated with a design certification rule are resolved when an exemption has been granted for a plant

referencing the design certification rule. Paragraph VI.B.5 describes how issues are resolved when a plant referencing the design certification rule obtains a license amendment for a departure from Tier 2 information. Paragraph VI.B.6 describes how issues are resolved when the applicant or licensee departs from the Tier 2 information on the basis of paragraph VIII.B.5, which waives the requirement to obtain NRC approval for such departures. Thus, once a matter (*e.g.*, an exemption in the case of paragraph VI.B.4) is addressed for a specific plant referencing a design certification rule, the adequacy of that matter *for that plant* would not ordinarily be subject to challenge in any subsequent proceeding or action (such as an enforcement action) listed in the introductory portion of paragraph IV.B, but there would not be any issue resolution on that subject matter for *any other plant*.

Each of the design certification rules in appendices A, B, and C to part 52 includes a Section VIII on change processes. These processes apply to changes depending upon the category of design information affected. For plant-specific Tier 2 information, the change process established in the rule mirrors, in large part, that in the former 10 CFR 50.59. The final rule amends paragraph VIII.B.5 of the design certification rules to conform the terminology in the § 50.59-like change process to that used in the current § 50.59. This amendment deleted references to unreviewed safety questions and safety evaluations, and conformed the evaluation criteria concerning when prior NRC approval is needed. Also, a definition was added to the design certification rules (paragraph II.G) for “departure from a method of evaluation” to support the evaluation criterion in paragraph VIII.B.5.b(8) of appendices A, B, and C to part 52.

In an earlier rulemaking (see 64 FR 53582; October 4, 1999), the NRC revised § 50.59 to incorporate new thresholds for permitting changes to a plant as described in the FSAR without NRC approval. For consistency and clarity, similar changes were adopted for part 52 applicants or licensees. Because of some differences in how the change control requirements are structured in the design certification rules, certain criteria contained in § 50.59 are not

necessary for or applicable to part 52 and are not being included in this rule. One criterion definition that the NRC did include was from § 50.59 for a “Departure from a method of evaluation,” which is appropriate to include in this rulemaking so that the eighth criterion in paragraph VIII.B.5.b of appendices A, B, and C to part 52, of the design certification rules will be implemented as intended.

Each of the design certification rules in appendices A, B, and C to part 52 includes a section on records and reporting. The NRC revised paragraph X.B.3.b in appendices A, B, and C to part 52 to change the reporting frequency from quarterly to semi-annually, and to extend the period of increased reporting frequency, relative to the frequency of 10 CFR 50.59(d) and 50.71(e)(4), from the date of a license application that references a design certification rule to the date that the Commission makes the finding under 10 CFR 52.103(g). The requirement to report plant-specific departures from, and updates to, the design control document during the interval from the application for a combined license until the Commission makes the finding under § 52.103(g) is to facilitate NRC’s monitoring of changes to the nuclear power plant, to achieve a common understanding of how the as-built facility conforms to the design information, and to adjust the inspection program to reflect the design changes.

The amendment to paragraph X.B.3.b to appendices A, B, and C to part 52 reduced the frequency of reporting during the period of construction and increased the frequency of reporting during the application review period. The NRC believes that these changes in the reporting burden balance each other and provide the information needed by the NRC to fulfill its responsibilities in the licensing of future nuclear power plants. In order to make the finding under § 52.103(g), the NRC must monitor the design changes made under Section VIII of appendices A, B, and C to part 52 of the design certification rules. Frequent reporting of design changes will be particularly important in times when the number of design changes could be significant, such as during the procurement of components and equipment, detailed design of

the plant before and during construction, and during preoperational testing. After the facility begins operation, the frequency of reporting would revert to the requirement in paragraph X.B.3.c, which is consistent with the requirements for operating plants.

Additional editorial changes to the rule language in appendices A, B, C, and D to part 52 are discussed in the NRC's responses to comments on Question 11 (see Section IV of this document).

15. Appendix N to Part 52—Combined Licenses for Nuclear Power Reactors of Identical Design.

Prior to this final rulemaking, appendix N in parts 50 and 52 contained the NRC's procedures governing the review and issuance of licenses for nuclear power plants of "duplicate design." Hearings for applications filed under appendix N in both parts 50 and 52 are governed by subpart D of part 2. In the March 2006 proposed rule, the NRC proposed deleting appendix N in part 52, and retaining these provisions only in part 50. Although no comment was received on this proposal, the NRC has decided to withdraw its proposal to delete appendix N in part 52. Since the preparation of the March 2006 proposed rule, several industry groups have announced their intention to seek combined licenses utilizing the same design. In view of this industry development, the NRC believes that there is potential utility to keeping the option of appendix N in part 52 open to potential combined license applicants. Accordingly, the NRC is retaining in part 52 the procedural alternative provided in appendix N to part 52, and to revise its language to make its provisions applicable to combined licenses using identical designs. As part of this revision, the NRC set forth more explicit direction on the information to be submitted, the NRC docketing review, notice, and the content of the EIS under appendix N

of part 52. However, the NRC decided against a wholesale revision of appendix N to part 52, together with conforming changes in part 51, inasmuch as these changes were not the subject of public comment, and because such a course of action would have delayed the overall part 52 rulemaking. Inasmuch as the changes to appendix N of part 52 constitute, in essence, revisions to the NRC's rules of procedure and practice (albeit located within part 52), the NRC may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

The overall concept of the revised appendix N to part 52 is that each application is to be treated as a separate application, with the exception of the common design. Hence, appendix N to part 52 requires separate applications, separate determinations of sufficiency for docketing, separate notices of docketing, and so forth. Sections requiring further explanation are discussed below.

Paragraph 2 of appendix N to part 52 requires that each application state that the applicant wishes to have the application considered under appendix N to part 52, and to list all of the applications that are to be treated together. This requirement ensures that the NRC is clearly informed of the intentions of all applicants, and to ensure that any individual reviewing the application can easily determine all of the applications using the identical ("common") design.

Paragraph 3 of appendix N to part 52 requires that each application identify the common design, and that the FSAR either incorporate by reference or include the common design. This ensures that there will be a single physical FSAR document that may be utilized by the NRC, and viewed by members of the public.

Paragraph 5 of appendix N to part 52 provides that, upon an NRC determination that each application is acceptable for docketing under 10 CFR 2.101, each application will be separately docketed (*i.e.*, each application will be given a separate docket number, but that

docket number may include a special designator signifying that it is part of a group of applications filed under appendix N to part 52). Ordinarily, the NRC will publish in the *Federal Register* a separate notice of docketing for each application, so that delays in the docketing of one application will not delay the docketing and subsequent technical review of other applications filed in accordance with appendix N to part 52. However, if circumstances allow (e.g., sufficiency review for multiple applications are completed simultaneously), the NRC may publish a single notice of docketing for multiple applications. The notice of docketing must state that the application will be processed under the provisions of 10 CFR part 52, appendix N and subpart D of part 2. As discussed under subpart D of part 2, the NRC also has discretion to either publish a notice of hearing for each application (possibly with the period for the filing of petitions to intervene running from the notice of hearing for the last application of the group), or to publish a joint notice of hearing for multiple applications.

Paragraph 6 of appendix N to part 52 sets forth the procedures by which the NRC will fulfill its obligations under NEPA. The NRC staff will prepare separate draft EIS for each application, but the NRC may conduct joint scoping on environmental issues related to the common design. If the applications reference a standard design certification or the use of a manufactured reactor, then the EIS must incorporate by reference the EA prepared for either the design certification or the manufacturing license, as applicable. The NRC has decided that the EA need not be included in the EIS. The Commission has required other documents to be incorporated into the FSAR in order to maximize the utility and ease of use of the FSAR, which is used repeatedly by the NRC staff over the lifetime of the licensed reactor. By contrast, the EIS is not typically utilized by the staff in such a manner; hence, the NRC deemed it unnecessary to require physical incorporation of the referenced design certification or manufacturing license EA into the referencing combined license EIS.

Paragraph 7 of appendix N to part 52 requires the ACRS to report on each of the combined license applications, as required by § 52.87. Each ACRS report is to be limited to the safety matters which are not relevant to the common design. In addition, the ACRS must issue a report on the safety of the common design - except for those matters relevant to the safety of a referenced design certification or manufactured reactor. Issuance of separate reports for each application will facilitate NRC staff internal review, consideration, and response to the ACRS report. It will also ensure that issues relevant to one application (*e.g.*, siting) are not addressed in the proceeding and hearing for another application. Issuance of a single report on the common design will also facilitate the issuance of the presiding officer's partial initial decision on the common design, as required by paragraph 8 of appendix N to part 52, and 10 CFR 2.405 of subpart D of part 2. The NRC notes that there may be circumstances where the common design extends beyond the design matters covered in a referenced design certification or manufactured reactor. For example, a common design could reference the use of a specific design certification and a common ultimate heat sink. In such circumstances, the ACRS would issue a common report limited to the safety matters for the ultimate heat sink.⁴

Paragraph 8 of appendix N to part 52 provides that the NRC will designate a presiding officer to conduct the portion of the hearing on matters related to the common design, and that the presiding officer must issue a partial initial decision on the common design. As discussed previously, hearing procedures for appendix N to part 52 proceedings are set forth in subpart D to part 2. To avoid duplication and possible (future) conflicts with subpart D to part 2, the NRC did not include in appendix N to part 52 further provisions addressing the conduct of hearings.

⁴The site-specific environmental impacts of the heat sink would ordinarily be addressed in each of the separate EISs prepared for each application, inasmuch as the environmental impacts would differ depending upon factors and characteristics at each site. Section 7 does not govern the scope of EISs prepared for common design elements.

D. Changes to 10 CFR Part 50.

1. General Provisions, § 50.2, *Definitions.*

New definitions are added as conforming changes to § 50.2. A definition of an *applicant* is added to clarify that a person or entity applying for Commission “permission or approval” is an applicant. This will ensure that part 50 requirements for applicants apply to a person or entity seeking an NRC approval not constituting a license, such as a standard design approval under part 52.

Definitions for *license* and *licensee* are added to clarify that early site permits and combined licenses under part 52 are licenses, and that holders of these types of licenses are licensees for purposes of part 50.

A definition for *prototype plant* is added to describe the type of nuclear reactor that is the subject of § 50.43(e). A prototype plant is a licensed nuclear reactor test facility that is similar to and representative of the first-of-a-kind nuclear plant in all features and size, but may have additional safety features. The purpose of the prototype plant is to perform testing of new or innovative design features for the first-of-a-kind nuclear plant design, as well as being used as a commercial nuclear power facility.

2. Requirement of License, Exceptions, § 50.10, *License required.*

Section 50.10 addresses the circumstances under which a license for a production or utilization facility is required, and describes activities which do not constitute “construction” for purposes of obtaining a license for a nuclear power plant. Section 50.10(b) formerly prohibited

a person from beginning construction of a production or utilization facility unless a construction permit has been issued. Inasmuch as activities constituting construction (as defined in § 50.10(b)) are authorized under a combined license, § 50.10(b) is revised to refer to combined licenses.

Formerly § 52.17(c) authorized an early site permit applicant to request authority to perform the activities allowed under § 50.10(e)(1). The NRC notes that the regulation did not provide for the holder of an early site permit to request authority to conduct § 50.10(e)(1) activities after the early site permit has been issued, and the NRC does not plan to change the current restriction. It will conserve the NRC's resources to consider the safety and environmental issues associated with § 50.10(e)(1) activities during the agency's consideration of the early site permit application. Late consideration of these requests after completion of the NRC's consideration of the application could entail substantial diversion of resources from other application reviews. For these reasons, the NRC does not allow an early site permit holder to request authority to perform activities allowed under § 50.10(e)(1) after issuance of the early site permit (the Commission notes that under former part 52, early site permit holders may not seek authority to perform activities allowed under § 50.10(e)(3) after issuance of the early site permit).

3. Classification and Description of Licenses.

a. Section 50.23, *Construction permits.*

Section 50.23 formerly provided that a construction permit for the construction of a production or utilization facility must be issued before issuance of a license for the facility, and

then only upon “due completion” of the facility. Section 50.23 is revised to clarify that if the NRC issues a combined license for a nuclear power plant under part 52, the construction permit and operating license are issued simultaneously (*i.e.*, are merged into a “combined license” under subpart C of part 52). This is consistent with Section 185.b of the AEA, which provides the NRC with explicit statutory authority to combine a construction permit and an operating license for a nuclear power plant into a single combined license. The Commission notes that § 50.23 is not limited to nuclear power plants; it also allows the NRC to combine, under Section 161.h of the AEA, a construction permit and operating license for production facilities or utilization facilities other than nuclear power plants.

4. Applications for Licenses, Certifications, and Regulatory Approvals; Form; Contents; Ineligibility of Certain Applicants.

a. Section 50.30, *Filing of application; oath or affirmation.*

Section 50.30 establishes the NRC’s general procedural requirements on filing of applications for licenses (including construction permits) for production and utilization facilities. The NRC is making conforming changes throughout § 50.30 to include necessary references to part 52 processes other than design certification (subpart H of part 2 governs the filing of standard design certification applications), *viz.*, early site permits, combined licenses, standard design approvals, and manufacturing licenses. In addition, § 50.30(a) is revised to ensure that the submission requirements governing applications (and amendments to these applications) in § 52.3 apply to part 52 processes other than design certification.

b. Section 50.33, *Contents of applications; general information.*

Section 50.33 identifies the general information that must be included in applications for licenses (including construction permits) for production and utilization facilities. Section 50.33(f) requires certain applicants for nuclear power plant licenses to submit information sufficient to determine whether the applicant has the financial qualifications to carry out, in accordance with the NRC's regulations, the activities for which a license or permit is sought. Section 50.33 is revised to require applicants for combined licenses to submit financial qualifications information. Financial qualifications information need not be submitted by applicants for early site permits, standard design certifications, standard design approvals, and manufacturing licenses. An NRC review to determine whether an applicant has adequate financial qualifications to conduct the activities authorized by an early site permit would contribute little, if anything, to providing reasonable assurance of adequate protection with respect to early site permit activities. Ordinarily, an early site permit authorizes no activities, unless the early site permit application requested authority to conduct the activities permitted under § 50.10(e)(1). The NRC has determined that no safety finding *per se* is necessary to authorize the licensee to conduct these activities. The NRC's review of a § 50.10(e)(1) application is focused on siting and environmental matters.

With respect to a standard design approval, the argument applies with even more force, inasmuch as a design approval authorizes no activities of any kind, and the finality associated with a design approval is significantly less than for an early site permit. The NRC concludes that no regulatory purpose appears to be served by a financial qualifications review for early site permits and standard design approvals. The NRC believes that there is little additional regulatory value in requiring a financial qualifications review for a manufacturing license. While

it is true that a lack of sufficient financial resources could result in inadequate manufacture of a reactor, under the NRC's proposed concept of a manufacturing license under subpart F of part 52, each manufactured reactor cannot be operated until ITAAC specified in the manufacturing license are successfully completed by the licensee authorized to construct the nuclear power facility using the manufactured reactor. Successful completion of the manufactured reactor's ITAAC should ensure that any problems with manufacture attributable to lack of financial resources of the manufacturing license holder can be identified before operation. Moreover, the licensee authorized to construct the facility (either under a construction permit or a combined license) using a manufactured reactor would have been subject to a financial qualifications review. This review should be sufficient to determine if the applicant has sufficient financial resources to carry out facility construction and the completion of the manufactured reactor's inspections, tests, and acceptance criteria. Finally, the NRC notes that it does not require the fabricators of safety-related and important to safety structures, systems, and components (SSCs) to be licensed and subject to a financial qualifications review. The NRC believes that a holder of a manufacturing license conducts activities which appear to be, in large part, analogous to these current non-licensed fabricators. Accordingly, the NRC concludes that a financial qualifications review of the applicant for a manufacturing license will not add significant regulatory value to justify the cost of such a review.

Section 50.33(g) addresses radiological emergency response plans for State and local government entities that must be submitted in applications for operating licenses. The final rule makes a conforming change to ensure that applicants for combined licenses must also submit this information, as well as applicants for early site permits who decide under § 52.17(b)(2)(ii) to seek NRC review and approval of complete emergency plans. In addition, § 50.33(g) provides requirements for the plume exposure pathway emergency planning zone (EPZ) and the ingestion pathway EPZ. The NRC has made a conforming change to § 50.33(g) in the final rule

to address early site permit applications that propose major features of emergency plans describing the EPZs under 10 CFR 52.17(b)(2)(i). Such provisions were inadvertently left out of the proposed rule. For an application for an early site permit that proposes major features of the emergency plans describing the EPZs, the change requires the descriptions of the EPZs, to meet the requirements of § 50.33(g). This is necessary for the NRC to be able to find that major features describing the EPZs are acceptable under § 52.18.

Section 50.33(h) formerly required applicants that propose to construct or alter a production or utilization facility to state in their application the earliest and latest dates for completion of the construction or alteration. This section is being revised in the final rule, based on public comments, to exclude combined license applicants. The NRC believes that combined license applications need not specify the earliest and latest date for completion of construction, in light of the amendment to Section 185 of the AEA that was made by the Energy Policy Act of 1992. By adding a new Section 185.b. of the AEA, the Commission believes that Congress intended that Section 185.b supersede Section 185.a of the AEA, so that the Section 185.a requirements for “stand-alone” construction permits, such as the need to specify the earliest and latest date for completion of construction, do not apply to the construction permit portion of a combined license under Section 185.b of the AEA. Accordingly, the final rule removes the requirements from §§ 50.33(h), 52.77, and 52.79(a)(39) that the combined license application specify the earliest and latest date for completion of construction.

Section 50.33(k) currently requires applicants for operating licenses to provide a report, as described in § 50.75, indicating how reasonable assurance that funds will be available for the decommissioning process. The final rule makes a conforming change to add a reference to combined licenses. The content of this report, reflecting the unique considerations of a combined license, is addressed separately in the revision to § 50.75.

c. Section 50.34, *Contents of construction permit and operating license applications; technical information.*

The NRC is changing the heading of § 50.34 from *Contents of applications; technical information* to read, *Contents of construction permit and operating license applications; technical information*. Section 50.34(a) currently provides the requirements for the technical contents of an application for a stationary power reactor construction permit, design certification or combined license, and § 50.34(b) provides the requirements for the technical contents of an application for a stationary power reactor operating license application. However, the former version of 10 CFR part 52 provides requirements for design certification and combined license applications that are not consistent with the current version of § 50.34. For example, former § 52.47 stated that an application for design certification must contain the technical information which is required of applicants for construction permits and operating licenses by part 50 which is technically relevant to the design and not site-specific. This would encompass requirements in both §§ 50.34(a) and (b). Also, former § 52.79 stated that applications for combined licenses must contain the technically relevant information required of applicants for an operating license by 10 CFR 50.34, which are found in § 50.34(b). In addition to the requirements for technical information in §§ 50.34(a) and (b), §§ 50.34(c) through (h) provide requirements for the contents of licensing applications related to security plans, compliance with Three Mile Island (TMI) related requirements, combustible gas control, and conformance with the standard review plan. Finally, the NRC notes that the subject of contents of an application is an administrative matter, than a strictly technical matter. Therefore, these administrative requirements for part 52 processes are more properly located in part 52, rather than in § 50.34. To provide maximum clarity in the requirements for the content of each of the different types of licensing applications, the NRC is revising § 50.34 to make it applicable to construction permit and operating license

applications only and to provide separate sections for the technical contents of applications for the other types of licenses or regulatory approvals in 10 CFR part 52 (early site permits in § 52.17, design certifications in § 52.47, combined licenses in § 52.79, design approvals in § 52.137, and manufacturing licenses in § 52.157). In its revisions to 10 CFR part 52, the NRC has brought forward the requirements from § 50.34 that are applicable to each of the licensing and approval processes in 10 CFR part 52. One exception to this structure is the provisions in § 50.34(f) related to compliance with TMI related requirements. Due to the length and complexity of the requirements in this paragraph, § 50.34(f) is being amended to indicate that each applicant for a design certification, design approval, combined license, or manufacturing license under part 52 of this chapter must demonstrate compliance with any technically relevant portions of the requirements in § 50.34(f)(1) through (3), except for paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v). The NRC chose this approach rather than repeat the requirements in each of the relevant sections in part 52. The NRC is adding the phrase “except for paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v)” in the last sentence of § 50.34(f) based on public comments. The commenters pointed out that proposed § 50.34(f) was inconsistent with proposed §§ 52.47(a)(17), 52.79(a)(17), 52.137(a)(17), and 52.157(e)(12), which included the exceptions that are being added to § 50.34(f) in the final rule.

d. Section 50.34a, *Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors*; and § 50.36a, *Technical specifications on effluents from nuclear power reactors*.

Section 50.34a requires that construction permit and operating license applications include a description of the equipment and procedures for the control of gaseous and liquid

effluents and for the maintenance and use of equipment installed in radioactive waste systems. Section 50.34a also requires these applications to include an estimate of (1) the quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations; and (2) the quantity of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations. In addition, § 50.34a requires a general description of the provisions for packaging, storage, and shipment offsite of solid waste containing radioactive materials resulting from treatment of gaseous and liquid effluents and from other sources. Section 50.34a is revised to clarify its applicability to the 10 CFR part 52 licensing and approval processes. Section 50.34a applies to combined licenses by virtue of the provision in former § 52.83, *Applicability of Part 50 provisions*, which states that all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits and operating licenses also apply to holders of combined licenses. Applicants for design certification are also required to include the information required by § 50.34a in their applications by virtue of the provision in former § 52.47(a)(1)(i), which states that an application for design certification must contain the technical information which is required of applicants for construction permits and operating licenses by 10 CFR part 50 which is technically relevant to the design and not site-specific. Former appendix O to 10 CFR part 52, Section O.3, explicitly required applicants for design approvals to include the applicable technical information required by § 50.34a. Finally, former appendix M to 10 CFR part 52, Section M.1, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses. Therefore, new provisions in § 50.34a(d) are adopted to address the applicable requirements for combined license applications that parallel the requirements for an operating license application. New provisions

in § 50.34a(e) are adopted to address the applicable requirements for applications for design approvals, design certifications, and manufacturing licenses to include: (1) a description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems; and (2) an estimate of the quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations, and the quantity of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations.

e. Section 50.36, *Technical specifications*.

Section 50.36(a) currently requires that each applicant for a license authorizing operation of a production or utilization facility include in its application proposed technical specifications in accordance with the requirements of § 50.36. The existing language in § 50.36(a) encompasses combined license applicants. However, applicants for design certification are also required to include proposed technical specifications in their applications by virtue of the provision in former § 52.47(a)(1)(i) stating that an application for design certification must contain the technical information required of applicants for construction permits and operating licenses by 10 CFR part 50 that is technically relevant to the design and not site-specific. Similarly, applicants for design approvals are also required to include proposed technical specifications in their applications by virtue of the provision in former appendix O to part 52, Section O.3, which states that the submittal for review of a standard design shall include the applicable technical information under §§ 50.34 (a) and (b), as appropriate.

Section 50.36 is revised to clarify that design certification and manufacturing license applications must also include proposed technical specifications. The new provisions in § 50.36(c) require each applicant for a design certification or a manufacturing license to include proposed generic technical specifications in its application for the portion of the plant that is within the scope of the design certification or manufacturing license application.

f. Section 50.36a, *Technical specifications on effluents from nuclear power reactors.*

Section 50.36a(a) requires each licensee of a nuclear power reactor to include technical specifications to keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable. The former language in § 50.36a(a) encompassed combined license holders. However, applicants for design certification are also required to include proposed technical specifications on effluents in their applications by virtue of the provision in current § 52.47(a)(1)(i) which states that an application for design certification must contain the technical information which is required of applicants for construction permits and operating licenses by 10 CFR part 50 which is technically relevant to the design and not site-specific. In addition, former appendix M to 10 CFR part 50, Section M.1, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety to manufacturing licenses. Therefore, Section 50.36a(a) is revised to state that each licensee of a nuclear power reactor and each applicant for a design certification or a manufacturing license will include technical specifications to keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable. The proposed rule did not include the provisions for manufacturing licenses.

However, proposed § 52.157(e)(18) did require manufacturing license applicants to include proposed technical specifications in accordance with § 50.36a. Therefore, it was clearly the NRC's intent that the provisions of § 50.36a be applicable to manufacturing license applications and the NRC has corrected this omission in the final rule.

Some commenters on the 2006 proposed rule identified an additional conforming change needed in § 50.36a that the NRC did not make in the proposed rule. Section 50.36(a)(2) currently requires that each licensee submit a report to the Commission annually that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous 12 months, including any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases. The NRC has modified this provision to state that each holder of a combined license is only required to begin submitting reports after the Commission has made the finding under § 52.103(g) that allows fuel load and operation. This would apply the requirements in §50.36a consistently for part 50 and part 52 licensees, because for a part 50 licensee, the annual reporting requirement is effective only after an operating license is issued.

The NRC is also making conforming changes to appendix I to 10 CFR part 50. These changes parallel the changes to §§ 50.34a and 50.36a.

g. Section 50.36b, *Environmental conditions.*

Section 50.36b authorizes the Commission to include conditions to protect the environment in each license authorizing operation of a production or utilization facility and each license for a nuclear power reactor facility for which the certification of permanent cessation of operations required under § 50.82(a)(1) has been submitted. These conditions are to be

derived from information contained in the environmental report and the supplement to the environmental report as analyzed and evaluated in the NRC record of decision. The conditions must identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

The NRC has made conforming changes to § 50.36b in the final rule to address all applicable part 52 licenses. The changes were made in response to public comments that highlighted the need for clarification in § 50.36b. The NRC provided proposed requirements for identifying environmental conditions on early site permits and combined licenses in the proposed rule in §§ 51.50(b) and (c). Requirements for identifying environmental conditions for construction permits were contained in former § 51.50 and proposed § 51.50(a). The proposed rule stated that, in an application for a construction permit, an early site permit, or a combined license, the applicant shall identify “any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter.” However, the NRC neglected to make the additional conforming changes to § 50.36b in the proposed rule. To correct this oversight, the NRC has modified § 50.36b in the final rule to make the requirements in this section consistent with the requirements in § 51.50. In doing so, the NRC has provided separate paragraphs for imposing conditions during construction and for imposing conditions during operation and decommissioning. Paragraph 50.36b(a) addresses requirements for imposing conditions on construction permits, early site permits, and combined licenses to protect the environment during construction. Paragraph 50.36b(b) addresses requirements for imposing conditions on licenses authorizing operation and licenses for a facility in decommissioning to protect the environment during operation and decommissioning. These changes provide consistency in requirements for environmental conditions across parts 50 and 51.

h. Section 50.37, *Agreement limiting access to Classified Information.*

Section 50.37 requires that a license or construction permit applicant agree in writing that it will not permit any individual to have access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. Section 50.37 also requires that this agreement be part of the application for a license or construction permit and that the agreement of the applicant shall be deemed part of the license or construction permit, whether stated or not. The former language of § 50.37 encompassed early site permit, combined license, and manufacturing license applicants under 10 CFR part 52 because these products are all licenses. However, the NRC is revising § 50.37 to encompass applicants for design certification and for standard design approvals under 10 CFR part 52 for consistency with the changes to 10 CFR part 25. Part 25 sets forth the NRC's requirements governing the granting of access authorization to classified information to certain individuals, and the Commission is making modifications to part 25 to reflect the licensing and regulatory approval processes in part 52. Accordingly, the Commission is revising to § 50.37. Section 50.37 is revised to require that an applicant for a license, construction permit, design certification, or design approval under part 52 agree in writing that it will not permit any individual to have access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. Section 50.37 also requires that this agreement be part of the application and be deemed part of the license, or construction permit, or NRC standard design approval whether stated or not. Section 52.54 is revised to include a new provision which requires that every standard design certification rule issued contain a provision that states that, after the Commission has adopted the final standard design certification rule, the applicant will not permit any individual to have

access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The NRC believes that these revisions, along with the complementary changes to parts 25 and 95, are necessary to ensure that access to classified information is adequately controlled by all entities applying for NRC licenses, design certifications, or design approvals.

5. Standards for Licenses, Certifications, and Approvals.

a. Section 50.40, *Common standards*.

This section sets forth standards for issuance of a license. Sections 50.40(a), (b), and (c) are revised to add conforming references to the additional licensing processes issued under 10 CFR part 52 that are applicable to these standards.

b. Section 50.43, *Additional standards and provisions affecting class 103 licenses and certifications for commercial power*.

The text and heading of this section are revised to clarify that certain additional standards and provisions for class 103 licenses apply to applications for combined licenses, design certifications, and manufacturing licenses issued under part 52, in addition to applications for construction permits and operating licenses issued under part 50. Section 50.43(e) is added to clarify that the requirements to demonstrate new safety features by testing, which were previously set forth in part 52, apply to applicants for operating licenses

issued under part 50 and applicants for combined licenses, design certifications, and manufacturing licenses issued under part 52. This amendment conforms to the goal of having reactor safety requirements in part 50 and procedural requirements in part 52. Only the requirements in § 50.43(e) apply to applications for design certification. Refer to the generic discussion on testing requirements for advanced reactors in Section V.B of this document.

c. Section 50.45, *Standards for construction permits, operating licenses, and combined licenses.*

This section is revised to include the standards for review of an application to alter a facility that was constructed under a combined license, after the findings under § 52.103(g) of this chapter are made by the Commission. Some commenters recommended that the proposed rule be revised to reference the applicable requirements in part 52 rather than the requirements in 10 CFR 50.31 through 50.43 and claimed that most of those requirements were moved to part 52 in the proposed rule. The Commission does not agree with that claim but does acknowledge that most of § 50.34 was moved to the contents of application section for each of the licensing processes in part 52. Therefore, § 50.45 was revised to set forth the standards for review of an application to alter a facility after the Commission makes the finding under § 52.103(g) of this chapter. The standards for issuance of a combined license are set forth in § 52.97.

d. Section 50.46, *Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.*

Section 50.46(a)(3) contains reporting requirements for changes to or errors in emergency core cooling systems (ECCS) evaluation models. Conforming references to design approvals, design certifications, and licenses issued under part 52 were made to § 50.46, so that the NRC will be notified of changes to or errors in acceptable evaluation models that were used in licenses, certifications, and approvals issued under part 52.

e. Section 50.47, *Emergency plans*, § 50.54(gg), and Appendix E to part 50, *Emergency planning and preparedness for production and utilization facilities*.

Section 50.47 and appendix E to 10 CFR part 50 contain emergency planning requirements for nuclear power plants. Prior to this rulemaking, these regulations did not clearly address early site permit or combined license applicants or holders. Accordingly, the NRC is making a number of changes in these regulations. Section 50.47(a)(1) states that no initial operating license for a nuclear power reactor will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, and that no finding under § 50.47 is necessary for issuance of a renewed nuclear power reactor operating license. The NRC is revising § 50.47(a)(1) to include provisions to address combined licenses and early site permits which include either complete and integrated plans or major features of the emergency plans. The NRC inadvertently left out provisions to address early site permits that include major features of the emergency plans in the proposed rule and a new provision has been added to address applicants in the final rule.

The NRC is making some additional changes to § 50.47(a)(1) in the final rule. Proposed § 50.47(a)(1)(ii) stated that “Except as provided in paragraph (e) of this section, no initial combined license under part 52 of this chapter will be issued unless a finding is made by the

NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.” In the final rule, the NRC is removing the phrase “except as provided in paragraph (e)” because paragraph (e) does not address issuance of the combined license, but, rather, addresses the Commission finding under § 52.103(g). Likewise, the NRC is making a change to paragraph (e) of this section in the final rule to remove the reference to paragraph (a) of this section.

Finally, the NRC is removing the statement in proposed § 50.47(a)(1)(iii) that “No finding under this section is necessary for issuance of a renewed early site permit.” The NRC included this provision in the proposed rule to be consistent with the existing requirement for operating licenses. However, upon further consideration, the NRC concludes that the basis for this exclusion for an operating license and for a combined license does not apply to an early site permit. The original license renewal rule, which limited the scope of matters to be addressed in the renewal proceeding, was based upon a determination that the regulatory process maintains and updates the licensing basis for operating licenses, that matters like the state of the emergency preparedness plans need not be addressed in license renewal. The bases for the license renewal rule described the process, in each substantive regulatory area, for maintaining and updating the current licensing basis. This logic does not directly apply to emergency preparedness information submitted in an early site permit application, because there is no maintenance or update requirement for the early site permit. Therefore, the NRC cannot exclude the need to address emergency preparedness in an early site permit renewal proceeding.

Section 50.47(c)(1) provides a process for operating license applicants that fail to meet the applicable standards of § 50.47(b). The NRC is revising § 50.47(c)(1) to clarify that this process is applicable to combined license applicants as well.

Section 50.47(d) formerly provided that no NRC or Department of Homeland Security (DHS) review, findings, or determinations concerning the state of offsite emergency preparedness or the adequacy of and capability to implement State and local or utility offsite emergency plans are required before issuance of an operating license authorizing only fuel loading or low-power testing and training (up to 5 percent of the rated power). Section 50.47(d) further stated that a license authorizing fuel loading and/or low-power testing and training may be issued after a finding is made by the NRC that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency and provides the standards by which the NRC will base such a finding. The NRC is adding a new § 50.47(e) to provide essentially parallel provisions for a combined license holder by stating that a combined license holder may not load fuel or operate except as provided in accordance with appendix E to part 50 and, because of the nature of the combined license process, the NRC is adding new § 50.54(gg) that would add a condition to all combined licenses. This is necessary to account for the fact that the combined license will already be issued at the time of the first full or partial participation exercise.

The NRC's findings regarding the state of emergency preparedness for a combined license holder will be taken into account in the NRC's review under § 52.103(g). The NRC will make its determination by judging whether the licensee has met the acceptance criteria in the combined license for the inspections, tests, and analyses related to the conduct of the first full or partial participation exercise under paragraph IV.F.2.a of appendix E to part 50. Paragraph 50.54(gg) states that if, following the conduct of the exercise required by paragraph IV.F.2.a of appendix E to part 50, DHS identifies one or more deficiencies in the state of offsite emergency preparedness, the holder of a combined license may operate at up to 5 percent of rated thermal power only if the Commission finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures

can and will be taken in the event of a radiological emergency. Paragraph 50.54(gg) also provides the standards by which the NRC will base such a finding.

The NRC is revising appendix E to part 50 to conform to the changes proposed for §§ 50.47 and 50.54. The introduction to appendix E to part 50 states that each applicant for an operating license is required by § 50.34(b) to include in the final safety analysis report plans for coping with emergencies. The NRC is adding a parallel statement for combined license applicants, and a statement that an early site permit applicant may submit emergency plans. The final rule also makes additional conforming changes to the second paragraph of the introduction that were inadvertently overlooked in the proposed rule. Similar modifications are proposed in Section III of appendix E to part 50 regarding the content of final safety analysis reports and site safety analysis reports for an early site permit. The NRC is making a correction to Section III in the final rule to replace references to the early site permit application with references to the site safety analysis report. The NRC is also adding a statement that the site safety analysis report for an early site permit which proposes major features must address the relevant provisions of 10 CFR 50.47 and 10 CFR part 50, appendix E, within the scope of emergency preparedness matters addressed in the major features. This is consistent with the requirements in § 52.17(b).

In Section IV of appendix E to part 50, the NRC is modifying paragraph F.2.a, to address combined licenses in addition to operating licenses. Paragraph F.2.a currently provides requirements regarding the conduct of full participation exercises and states that a full participation exercise shall be conducted within 2 years before the issuance of the first operating license for full power of the first reactor. Paragraph F.2.a also requires that, if the full participation exercise is conducted more than 1 year before issuance of an operating license for full power, an exercise which tests the licensee's onsite emergency plans shall be conducted within 1 year before issuance of an operating license for full power. The NRC is designating

the requirements for operating licenses as paragraph F.2.a.i, and adding a new paragraph F.2.a.ii that contains the requirements for combined licenses. Paragraph F.2.a.ii states that, for a combined license, the first full participation exercise must be conducted within 2 years of the scheduled date for initial loading of fuel and operation under § 52.103. Paragraph F.2.a.ii also requires that, if the first full participation exercise is conducted more than 1 year before the scheduled date for initial loading of fuel and operation under § 52.103, an exercise which tests the licensee's onsite emergency plans must be conducted within 1 year before the scheduled date for initial loading of fuel and operation under § 52.103. The modifications further state that, if DHS identifies one or more deficiencies in the state of offsite emergency preparedness as the result of the first full participation exercise, or if the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) will apply, as previously discussed.

The NRC is adding a new paragraph IV.F.2.a.iii to appendix E to part 50 to require that, if the applicant has an operating reactor at the site, an exercise, either full or partial participation, be conducted for each subsequent reactor constructed on the site. This exercise may be incorporated in the exercise requirements of paragraphs (2)(b) and (2)(c) of Section IV.F. If DHS identifies one or more deficiencies in the state of offsite emergency preparedness as the result of this exercise for the new reactor, or if the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply just as they do for the first reactor at a site. This new provision is desirable because of the nature of ITAAC for emergency preparedness requirements. The emergency preparedness ITAAC, specifically ITAAC that will be demonstrated through an exercise, provide the necessary reasonable assurance for programs and facilities associated with the yet-unbuilt

reactor. Recent agreements between the NRC and external stakeholders on emergency preparedness ITAAC are based on the understanding that ITAAC on the emergency preparedness exercise would serve to demonstrate various aspects of emergency preparedness (e.g., programs and facilities) that did not warrant their own specific/detailed ITAAC. For example, there is no ITAAC for determining whether an adequate staffing roster exists for the technical support center or emergency offsite facility, but its existence and adequacy could be demonstrated during an exercise. Therefore, appendix E to part 50 requirements for emergency preparedness exercises must be included for the current concepts regarding emergency preparedness ITAAC to be viable. With regard to subsequent reactors, those aspects of an exercise which address currently untested (*i.e.*, unexercised) aspects of emergency preparedness for the proposed new reactor must be addressed in new emergency preparedness ITAAC for the subsequent reactor. If various generic exercise-related aspects of emergency preparedness for the site have been previously addressed and satisfied, then there would be no ITAAC for those emergency preparedness aspects for subsequent reactors.

The NRC is also modifying Section V of appendix E to part 50, which states that no less than 180 days before the scheduled issuance of an operating license for a nuclear power reactor or a license to possess nuclear material, the applicant's detailed implementing procedures for its emergency plan shall be submitted to the Commission. Paragraph V also requires that licensees submit any changes to the emergency plan or procedures to the NRC within 30 days of these changes. The NRC is clarifying that paragraph V is also applicable to COL holders by stating that they must submit their detailed implementing procedures for their emergency plans to the NRC no less than 180 days before the scheduled date for initial loading of fuel. The wording of this requirement has been changed slightly in the final rule. In the proposed rule, this provision required that COL holders submit their detailed implementing procedures for their emergency plans to the NRC no less than 180 days before the date that

the Commission authorizes fuel load and operation under § 52.103. The NRC has modified the provision to make the target date 180 days before scheduled date for initial loading of fuel because this will be a known date whereas the licensee would not know the date that the Commission will make the § 52.103(g) finding. This change is also consistent with other requirements in appendix E that are tied to the scheduled date for initial fuel load.

f. Section 50.48, *Fire protection.*

Section 50.48(a)(1) is revised to clarify that holders of an operating license issued under part 50 and a combined license issued under part 52 must have a fire protection plan. Section 50.48(a)(4) is added to clarify that applications for design approvals, design certifications, and manufacturing licenses issued under part 52 must meet the fire protection design requirements set forth in general design criterion 3 of appendix A to part 50.

g. Section 50.49, *Environmental qualification of electric equipment important to safety for nuclear power plants.*

Section 50.49(a) is revised to clarify that these programmatic requirements apply to applicants for and holders of operating licenses issued under part 50 and combined licenses and manufacturing licenses under part 52.

h. Section 50.54, *Conditions of licenses;* and § 50.55, *Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.*

Section 50.54 sets forth various provisions that are deemed to be conditions “in every license issued,” while § 50.55 sets forth the provisions deemed to be conditions of every construction permit. In making the conforming changes to these regulations to reflect part 52, the NRC has decided to maintain this dichotomy. Conditions applicable to part 52 processes which are either licenses or prerequisites to licenses, and do not address activities analogous to construction for which a construction permit license is required under the AEA, are addressed in § 50.54. By contrast, conditions applicable to part 52 processes which address construction activities, or activities analogous to construction for which a construction permit license is required under the AEA, are covered in § 50.55. Combined licenses represent a special case, inasmuch as they address both construction and operation. The NRC addresses combined licenses by placing the conditions applicable only to construction in §50.55, which indicates that these conditions are applicable until the date that the Commission makes the finding under § 52.103(g). Conditions which are applicable during construction and operation or only during operation are set forth in § 50.54. The NRC is revising the introductory paragraph of § 50.54 to refer to combined licenses, and to exclude manufacturing licenses from its provisions. The NRC is making revisions to § 50.54 in the final rule based on public comments. In the proposed rule, the NRC did not distinguish which provisions in § 50.54 are applicable only during operation from those that are applicable during both construction and operation. In the final rule, the NRC has revised the introductory paragraph to indicate which provisions are applicable only after the Commission makes the finding under § 52.103(g). In making these revisions, the NRC determined that the provisions that need to be applied during both construction and operation are paragraphs (a) through (h), (o), (p), (q), (t), (v), and (aa) through (ee). All of these provisions have some requirements that will be implemented prior to the Commission finding under § 52.103(g).

In addition, the NRC is adding paragraphs (r) and (u) to the list of provisions in the introduction that are not applicable to combined licenses. This is because paragraph (r) only applies to research and test reactor facilities and paragraph (u) was only applicable for 60 days after the amendment to § 50.54 that added paragraph (u). Finally, the NRC is also revising the first sentence of the introduction to indicate that paragraphs (r) and (gg) do not apply to nuclear power reactor operating licenses. In the proposed rule, the introduction stated that they did not apply to operating licenses, which would have included research and test reactor operating licenses.

The NRC is revising § 50.54(a)(1) to indicate that the quality assurance (QA) requirements applicable to operation, as described in a combined license holder's SAR, become effective 30 days before the scheduled date for the initial loading of fuel.

The NRC is revising § 50.54(i-1) to indicate its applicability to combined licenses. Specifically, § 50.54(i-1) requires that within 3 months after the date that the Commission makes the finding under § 52.103(g) for a combined license, the licensee shall have in effect an operator requalification program that must, as a minimum, meet the requirements of § 55.59(c) of this chapter.

The NRC has added changes to § 50.54(p) and (q) in the final rule. The changes to paragraph (p) are being made to include references to appropriate part 52 sections in addition to the existing references to part 50 sections. The change to paragraph (q) is being added to include a statement that, for combined licenses, the requirement to follow and maintain in effect emergency plans which meet the standards in § 50.47(b) and the requirements in appendix E of part 50 is only applicable after the Commission makes the finding under § 52.103(g). However, the remainder of the requirements in paragraph (p) apply from the time the combined license is issued (e.g., requirements to retain records of emergency plan changes). This is consistent with the change made to the introductory paragraph of § 50.54 discussed earlier in this section.

The NRC is adding a new § 50.54(gg). These revisions are discussed with related requirements in Section IV.D.4.f of this document, “Section 50.47, Emergency plans, § 50.54(gg), and appendix E to part 50.”

Although the NRC generally views § 50.55 as the appropriate section in part 50 for specifying the conditions applicable to construction permits and part 52 processes analogous to construction permits, the NRC does not believe that all of the conditions in § 50.55 should apply equally to all of the part 52 processes. Accordingly, the introductory text to § 50.55 is revised to specify which paragraphs apply to a construction permit, early site permit, combined license, and manufacturing license.

Sections 50.55(a) and (b) of the March 2006 proposed rule would have required a combined license to state the earliest and latest dates for completion of construction or modification, and to provide for forfeiture of the combined license if the construction or modification is not completed by the stated date. The Commission has reconsidered this position and has decided to remove this requirement from the final rule. The statutory requirement for a construction permit to state the earliest and latest date for completion of construction is now contained in Section 185.a of the AEA. The combined license, by contrast, is address in Section 185.b. The Commission believes that in the absence of specific language regarding the restriction in paragraph a. applicable to combined licenses in paragraph b., the combined license is not subject to any of the statutory restrictions in paragraph a. The NRC believes that the provisions of Section 185 of the AEA do not apply to a manufacturing license, inasmuch as a manufacturing license is not, *per se*, a construction permit. Accordingly, no earliest and latest date for completion of manufacture would be required to be stated in a manufacturing license.

Section 50.55(c) makes the license conditions in § 50.54 also apply to construction permits, unless otherwise modified. In the proposed rule, the NRC revised this paragraph to

add a reference to combined licenses. However, upon further consideration, the NRC has determined that no change to § 50.55(c) is necessary because the introduction to § 50.54 outlines which provision in that section apply to combined licenses.

Section 50.55(e) addresses the obligation of holders of construction permits and their contractors and subcontractors, to report defects constituting a substantial safety hazard. These requirements, which implement Section 206 of the ERA, as amended, are comparable to the requirements in 10 CFR part 21. As discussed with respect to the NRC's changes to part 21, the NRC is retaining the current regulatory structure, whereby persons and entities engaged in activities constituting construction (and their contractors and subcontractors) are subject to § 50.55(e), and persons and licensees who are authorized to operate a nuclear power plant (and their contractors and subcontractors) are subject to part 21. Inasmuch as a combined license under part 52 authorizes both construction and operation, a combined license holder would be subject to the reporting requirements in § 50.55(e) from the date of issuance of the combined license until the Commission makes the finding under § 52.103. Thereafter, the combined license holder would be governed by the reporting requirements in part 21. The manufacture of a nuclear power reactor under a manufacturing license is the functional equivalent of construction. Accordingly, the NRC's view is that the holder of a manufacturing license should be subject to reporting under § 50.55(e). Standard design approvals under subpart E to part 50 (former appendix M to part 52) and design certifications under subpart B of part 52 are not directly associated with construction, and the NRC believes that their reporting should be addressed under part 21. Accordingly, the NRC is revising § 50.55(e)(1) to provide that the reporting requirements in § 50.55(e) apply to a holder for a combined license (until the NRC makes the finding under § 52.103(g)), and a manufacturing license under part 52. As discussed further in Section J on part 21 of this document, early site permits do not authorize

“construction” or its functional equivalent. Therefore, early site permits are subject to the requirements of part 21 rather than § 50.55(e) under the final rule.

Section 50.55(f) sets forth the NRC’s requirements with respect to compliance with the QA requirements in 10 CFR part 50, appendix B, and implementation of the construction permit holder’s QA program as described in its SAR. Comparable provisions applicable to holders of operating licenses are contained in § 50.54(a); requirements governing the SAR’s description of the QA program are contained in § 50.34. A detailed discussion of all changes related to QA requirements can be found in Section IV.D.13.b of this document.

i. Section 50.55a, *Codes and standards.*

Section 50.55a provides requirements relating to codes and standards for construction permits and operating licenses for boiling or pressurized water-cooled nuclear power facilities. The NRC is revising § 50.55a to clarify how the regulations in § 50.55a apply to approvals, certifications, and licenses issued under 10 CFR part 52. Section 50.55a formerly applied to combined licenses by virtue of the provision in current § 52.83, which stated that all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits and operating licenses also apply to holders of combined licenses. Also, § 50.55a formerly applied to design certifications by virtue of the provision in former § 52.48, which states that design certification applications will be reviewed for compliance with the standards set out in 10 CFR part 50 as it applies to applications for construction permits and operating licenses for nuclear power plants, and as those standards are technically relevant to the design proposed for the facility. Although former appendix O to part 52 does not explicitly require applicants for design approvals to comply with the requirements of § 50.55a, the NRC is requiring design approval holders to comply with § 50.55a because the NRC believes that the requirements for a design

approval should be the same as the requirements for design certification, given that the reviews performed by the NRC staff for the two products are essentially identical. Finally, appendix M to part 52, Section M.1, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses. Therefore, the NRC is modifying § 50.55a to state that each combined license for a utilization facility is subject to the conditions in § 50.55a, but is only subject to the conditions in §§ 50.55a(f) and (g) after the NRC makes the finding under § 52.103. The modifications to § 50.55a also state that each manufacturing license, design approval, and design certification application is subject to the conditions in §§ 50.55a(a), (b)(1), (b)(4), (c), (d), (e), (f)(3), and (g)(3), which are the provisions related to nuclear power facility design.

j. Section 50.59, *Changes, tests, and experiments.*

This section presents a change process for information contained in the FSAR. Section 50.59(b) is revised to clarify that this change process is applicable to holders of operating licenses issued under part 50 and combined licenses issued under part 52. If the combined license references a design certification rule, then the information in the design control document is controlled by the change process in the applicable design certification rule. Section 50.59(d)(2) is revised to conform the frequency that summary reports are submitted for holders of combined licenses with the frequency set forth in the design certification rules. Section 50.59(d)(3) is revised to clarify that the requirement for maintaining records applies to holders of operating licenses issued under part 50 and combined licenses issued under part 52.

k. Section 50.61, *Fracture toughness requirements for protection against pressurized thermal shock events.*

This section is revised to clarify that the fracture toughness requirements apply to an operating license for a pressurized water reactor issued under part 50 or a combined license for a pressurized water reactor issued under 10 CFR part 52.

l. Section 50.62, *Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.*

Paragraph (d) of § 50.62 provides implementation requirements for the requirements of the section. This paragraph is revised to indicate that these implementation requirements only apply to light-water-cooled nuclear power plant operating licenses issued before the effective date of this final rule. Section 50.62 is revised to require each light-water-cooled nuclear power plant operating license application submitted after the effective date of this final rule to submit information in its final safety analysis report demonstrating how it will comply with paragraphs (c)(1) through (c)(5) of § 50.62. Similarly, the NRC is adding provisions to §§ 52.47, 52.79, 52.137, and 52.157 requiring that applicants for standard design certifications, combined licenses, standard design approvals, and manufacturing licenses include the information required by this section in their final safety analysis reports.

m. Section 50.63, *Loss of all alternating current power.*

Conforming changes are made to this section to clarify that the requirements for station blackout apply to applications for construction permits, combined licenses, design approvals, design certifications, manufacturing licenses, and operating licenses.

n. Section 50.65, *Requirements for monitoring the effectiveness of maintenance at nuclear power plants.*

This section presents the requirements for a maintenance program at nuclear plants. Section 50.65(a) is revised to clarify that holders of operating licenses issued under part 50 and combined licenses issued under part 52 must have a maintenance program. In the proposed rule, § 50.65(c) was revised to specify that for new licenses issued after the effective date of this regulation, the maintenance program must be implemented 30 days before the initial fuel loading of the reactor. Commenters recommended that NRC should not require implementation of the maintenance rule prior to fuel load when not all systems will have been placed in service. The NRC agrees with this comment and has deleted the proposed revision to § 50.65(c). The NRC expects that licensees will have the maintenance program operational by the time that initial fuel loading has been authorized.

6. Inspections, Records, Reports, Notifications.

a. Section 50.70, *Inspections.*

Section 50.70(a) requires that each licensee and each holder of a construction permit allow inspection, by duly authorized representatives of the Commission, of its records,

premises, activities, and of licensed materials in possession or use, related to the license or construction permit as may be necessary to effectuate the purposes of the AEA. The language in § 50.70(a) encompasses combined license holders and manufacturing license holders because they are licensees. In addition, the provision in former § 52.83, states that all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits and operating licenses also apply to holders of combined licenses. Also, former Section M.1 of appendix M to part 52, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses. Section 50.70(a) is revised to clarify that these inspection requirements also apply to holders of early site permits under 10 CFR part 52. An early site permit is a partial construction permit and therefore should be subject to the same inspection requirements as a construction permit. In addition, the NRC is clarifying that the inspection requirements also apply to applicants for licenses, construction permits, and early site permits. It is common for applicants to perform activities related to NRC regulations before issuance of the license or permit for which they are applying and it has been the NRC's practice to inspect these activities whenever they are performed. Therefore, the modification to require that the inspection requirements in § 50.70(a) apply to applicants is simply a codification of the NRC's current practices.

Section 50.70(b)(1) require that each licensee and each holder of a construction permit provide rent-free office space for the exclusive use of NRC inspection personnel. The existing language in this provision encompasses combined license holders and manufacturing license holders. Section 50.70(b)(2) provides requirements regarding the space to be provided for a site with a single power reactor facility licensed under 10 CFR part 50 and for sites containing multiple power reactor units. The NRC is revising § 50.70(b)(2) to clarify that these

requirements also apply to sites for combined license holders under 10 CFR part 52 and to facilities issued manufacturing licenses under 10 CFR part 52.

b. Section 50.71, *Maintenance of records, making of reports.*

Section 50.71 establishes the NRC's requirements for maintenance and retention of records and reports, and updating of FSARs. Section 50.71(a) requires each licensee and each holder of a construction permit to maintain all records and make all reports as may be required by license, or by the NRC's regulations. The former language does not apply to non-licensees, such as holders of standard design approvals and applicants for standard design certifications, even though it would appear that these requirements should apply. Accordingly, the NRC is revising § 50.71(a) to make its provisions applicable to holders of standard design approvals and all applicants for design certification during the period of NRC consideration of the application for design certification, and those applicants for design certification whose designs are certified via rulemaking in accordance with subpart B of 10 CFR part 52.

Section 50.71(c) specifies that the default record retention period (*i.e.*, the period that applies if a record retention period is not specified by the regulation requiring the record) ends when the NRC "terminates the facility license." A manufacturing license is not a "facility" license, inasmuch as subpart F of part 52 is limited to the manufacture of reactors, not a "facility." Finally, some licenses (*e.g.*, early site permits and manufacturing licenses) may either be terminated by the NRC, or "expire" as a matter of law at the end of their term. Accordingly, the NRC is revising § 50.71(c) to establish the records retention period and to properly refer to manufacturing licenses, early site permits, and construction permits.

Section 50.71(e) establishes the updating requirements for the FSAR, including the information that must be included in each update. The former regulation, however was deficient in two respects. First, it did not address the updating requirements for combined license holders where the combined license references a standard design certification. Second, the regulation, if applied to manufacturing licenses under subpart F of part 52, imposed unnecessary regulatory burden with respect to periodic updating. The NRC's concept of a manufacturing license under subpart F of part 52 is for a relatively stable, unchanging design. Hence, there should be no need for periodic updating. Rather, the updating should occur only as the result of NRC-approved changes to the design.

Accordingly, the NRC is revising § 50.71(e) to specify the FSAR updating requirements for combined license holders where the license references a standard design certification. In addition, current § 50.71(f) is redesignated as § 50.71(g), and a new § 50.71(f) is added, addressing the FSAR update requirements for a manufacturing license. Section 50.71(f) is revised to require the holder of the manufacturing license to update the FSAR to reflect any modifications to the design of the reactor authorized to be manufactured which have been approved by the NRC under § 52.171, or any new analyses requested to be performed by the NRC. Periodic updating of a FSAR for a manufacturing license is not required by § 50.71(f), inasmuch as the NRC's concept for a manufacturing license is for the design of the reactor authorized to be manufactured to be stable with no changes except as specifically approved by the NRC as necessary for adequate protection to public health and safety or common defense and security, or to ensure compliance with the NRC's requirements in effect at the time of issuance of the manufacturing license. The provision in § 50.71(f) requiring the FSAR for a manufacturing license to be updated to reflect new safety analyses required by the NRC is analogous to the existing updating requirement in § 50.71(e). This assures that new analyses

performed to demonstrate the continuing adequacy of the unchanged manufactured reactor design are appropriately reflected in the FSAR.

c. Section 50.72, Immediate notification requirements for operating nuclear power reactors.

Section 50.72 currently requires holders of operating licenses under part 50 for nuclear power plants to notify the NRC Operations Center via the Emergency Notification System of the declaration of any of the emergency classes specified in the licensee's approved emergency plan and of certain non-emergency events. The NRC's regulatory interest in these events also extends to nuclear power plants operating under a combined license under subpart C of part 52, but the former language did not impose the notification requirements on combined license holders. Accordingly, in a conforming change in the final rule, the NRC is extending the notification requirements to holders of combined licenses under part 52 after the Commission has made the finding under § 52.103(g). The NRC did not include a conforming change to this section in the proposed rule. However, based on public comments, the NRC is including the change in the final rule to make it clear that the requirements of § 50.72 only apply to a combined license holder after the Commission makes the finding under § 52.103(g). The NRC is not extending the notification requirements to other part 52 processes because the events to be reported under the existing rule concern events which can only occur upon fuel load and operation, and the remaining part 52 licensing and regulatory approval processes do not authorize fuel load or operation.

d. Section 50.73, Licensee event report system.

Section 50.73 requires holders of operating licenses under part 50 for nuclear power plants to submit licensee event reports (LERs) on the occurrence of certain operating events to the NRC. LERs facilitate the NRC's oversight of operating nuclear power plants, by alerting the NRC to the occurrence and underlying causes of events having potential safety implications. The NRC's regulatory interest in these events also extends to nuclear power plants operating under a combined license under subpart C of part 52, but the former language did not impose the LER requirement on combined license holders. Accordingly, in a conforming change, the NRC is extending the LER reporting requirements to holders of combined licenses under part 52 after the Commission has made the finding under § 52.103(g). The final rule does not extend the LER requirement to other part 52 processes, because the events to be reported under the existing rule concern events which can only occur upon fuel load and operation, and the remaining part 52 licensing and regulatory approval processes do not authorize fuel load or operation.

e. Section 50.75, *Reporting and recordkeeping for decommissioning planning.*

The requirements in § 50.75 are intended to ensure that entities who construct and ultimately operate a nuclear power plant will have sufficient funds at the end of the operational life of the plant to complete the decommissioning of the plant. Section 50.75 requires a nuclear power plant operating license application to address the predicted costs of decommissioning, provide financial assurance by one of the means specified in the regulation, and submit evidence that one or more of these means has been established. Section 50.75 also requires the operating license holder to update the cost estimates for decommissioning on an annual basis, and to submit reports to the NRC every 2 years describing, *inter alia*, any adjustments to

the amount of funds collected annually to reflect any changes in projected decommissioning cost. When a plant is within 5 years of its projected end of its operation, the reports must be submitted annually, and a site-specific decommissioning cost estimate must be submitted. Some of these requirements are directed at the two phase licensing process in 10 CFR part 50, in which the NRC issues a construction permit followed by an operating license. These requirements are not well-suited to the combined license process under part 52. For example, requiring the combined license applicant to comply with the current requirement in § 50.75(b)(4) that the operating license applicant submit a copy of the financial instrument obtained to satisfy the requirements of § 50.75(e), would place a more stringent requirement on the combined license applicant, inasmuch as that applicant would be required to fund decommissioning assurance at an earlier date as compared with the operating license applicant.

To address these discrepancies, the NRC is revising § 50.75 to address decommissioning funding assurance for combined licenses. Under the final rule, the combined license applicant must submit a decommissioning report as required by § 50.33(k), but it need not obtain a financial instrument to fund decommissioning or to submit a copy to the NRC. Instead, under § 50.75(b)(1) and (4), the combined license application must contain a certification that the financial assurance will be provided no later than 30 days after the NRC publishes notice in the *Federal Register* under § 52.103(a). See § 50.75(b)(1).

The proposed rule would have required the combined license holder to submit, by March 31 of each year until the date that the NRC authorizes fuel load under § 52.103(g), an updated certification of the information required by paragraph (b)(1). The proposed rule also would have required the combined license holder to submit, no later than 30 days after the Commission publishes notice in the *Federal Register* under § 52.103(a), a certification that financial assurance is being provided in the relevant amount together with a copy of the financial instrument obtained to satisfy the requirements of § 50.75(e). Once the Commission

has made the finding under § 52.103, the proposed rule would have required the combined license holder to be subject to the reporting and updating requirements as an operating license holder under part 50, including the requirements applicable when the plant is within 5 years of the projected end of operation. A commenter objected to the annual reporting requirement, arguing that an annual update during the construction period would serve no purpose and is unnecessary and unduly burdensome. The commenter proposed that the holder be allowed to adjust or update the original certification at the time construction is complete and the plant is ready to begin operation. Upon further consideration, the Commission has decided to modify the final rule by eliminating the requirement for annual reports, and instead requiring the updating reports 2 years and 1 year before the date scheduled for initial loading of fuel load (as this term is used in § 52.103). The Commission's objective is to have sufficient time to evaluate the projected costs of decommissioning, and any licensee-proposed changes in the financial assurance mechanism for funding before fuel is loaded into the reactor and operation commences. This will allow the Commission to take any necessary regulatory action before fuel loading and commencement of operation.

The final rule requires that no later than 30 days after the Commission publishes notice in the *Federal Register* under § 52.103(a), the combined license holder must submit a report to the NRC. The report must contain a certification that financial assurance is being provided in an amount specified in the licensee's most recent updated certification (*i.e.*, the certification provided 1 year before the scheduled date for initial loading of fuel, in accordance with the first sentence of § 50.75(e)(3)). The certification must include a copy of the financial instrument obtained to provide decommissioning funding assurance. The requirements in paragraph (f)(1) of § 52.103(a), which are applicable to the combined license holder after the Commission has made the finding under § 52.103, are adopted in the final rule without change from the proposed rule.

The § 50.75 decommissioning funding requirements do not apply to an applicant for, and holder of, a manufacturing license under part 52. The NRC did not intend, when it first adopted § 50.75, to subject holders of manufacturing licenses to the requirements of that section. It is clear from the words of former § 50.33(k)(1) that the rule applies only to applications for operating licenses for production and utilization facilities. A manufacturing license by itself does not authorize either fuel load or operation, which are the activities necessitating the expenditure of funds for decommissioning. Therefore, there is no need for a holder of a manufacturing license, who does not intend to operate the reactor being manufactured to provide funding.

7. US/IAEA Safeguards Agreement.

a. Section 50.78, *Installation information and verification.*

Since 1980, the United States International Atomic Energy Agency (IAEA) Safeguards Agreement has allowed IAEA inspection and verification activities at U.S. facilities that the IAEA selects from the U.S. Eligible Facilities List. The safeguards agreement is implemented under the Nuclear Non-Proliferation Treaty, which provides assurance that all nuclear materials declared to be in peaceful use are not diverted to potential use in nuclear explosives. Although 10 CFR part 75 contains most of the NRC requirements intended to implement the installation, inspection, and verification provisions of the Safeguards Agreement with IAEA, § 50.78 requires each holder of a construction permit to submit certain information on Form N-71, permit verification by representatives of the IAEA, and take any other action necessary to implement the Safeguards Agreement. Inasmuch as combined licenses authorize construction of a nuclear power plant at a fixed site, the provisions of § 50.78 should also apply to a holder of a

combined license under part 52. Accordingly, § 50.78 is revised to specify that holders of combined licenses must, if requested by the NRC, submit installation information on Form N-71, permit verification of that information by the IAEA, and take other action as may be necessary to implement the Safeguards Agreement, in the manner set forth in § 75.6, and §§ 75.11 through 75.14.

8. Transfers of Licenses—Creditors' Rights—Surrender of Licenses.

a. Section 50.80, *Transfer of licenses.*

Section 50.80 implements Sections 101 and 184 of the AEA, which require Commission approval for the transfer of a license for a production or utilization facility, including a nuclear power reactor. Section 50.80(a) explicitly refers to transfers of a “license for a production or utilization facility...,” which would include construction permits under part 50, as well as all licenses and permits issued under part 52. However, to explicitly recognize the applicability of § 50.80(a) to both permits under parts 50 and 52 and all licenses under part 52, § 50.80(a) is revised to explicitly refer to permits under parts 50 and 52, and licenses under part 52. The proposed rule would have only made these clarifying revisions. A commenter on the proposed rule stated that some of the requirements in § 50.80 are not relevant to transfers of an ESP. The NRC agrees, and has revised the final rule to specify which criteria are applicable to transfer of an ESP. Specifically, paragraph (b)(1)(ii) requires an application for transfer of an ESP to include as much of the information described in §§ 52.16 and 52.17 with respect to the identity and technical qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. This change removes the requirement for

the applicant for transfer of an ESP to address financial qualifications since this is not required of an initial ESP applicant. In addition, this change removes the provision that the NRC may require additional information as part of an ESP transfer with respect to data on proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards. Information on these subject matters are not relevant to an ESP transfer, inasmuch as an ESP does not authorize the holder to possess radioactive material.

The NRC declines to adopt the suggestion of a commenter who suggested that the statement of considerations clarify when a transfer of an ESP is necessary. The NRC's revision to § 50.80 is a conforming change to a procedural regulation, the process by which the NRC processes and determines a transfer of a license. Section 50.80 does not, by itself, specify the circumstances for which a license transfer is necessary; it simply addresses what procedures must be followed if a license transfer request is received. Therefore, the NRC does not believe that it is necessary or desirable to provide such guidance in the context of this rulemaking.

b. Section 50.81, *Creditor regulations.*

Section 50.81 implements Section 184 of the AEA, which requires the consent of the Commission for the creation of any mortgage, pledge or other lien upon any Commission-licensed facility or special nuclear material. To ensure that the reach of § 50.81 is as broad as the statutory requirement, the NRC is revising the definition of *license* and *facility*. The definition of *license* in this section is revised to explicitly refer to all licenses under 10 CFR, and early site permits under part 52. The definition of *facility* is revised to add a new paragraph which explicitly refers to an early site permit under part 52, and a reactor manufactured under a manufacturing license under part 52.

9. Amendment of License or Construction Permit at Request of Holder.

a. Section 50.90, *Application for amendment of license or construction permit*; § 50.91, *Notice for public comment; State consultation*; and § 50.92, *Issuance of amendment*.

Sections 50.90, 50.91, and 50.92 govern the procedures and criteria for NRC consideration and issuance of amendments to licenses and construction permits. The regulations do not clearly address early site permits, combined licenses, or manufacturing licenses. Accordingly, the NRC is making a number of changes in these regulations.

Section 50.90 provides that applicants for amendment of a license or construction permit must file their application with the NRC as described in § 50.4, following the form prescribed for the original application. Although the term, *license*, as amended in § 50.2 includes combined licenses, manufacturing licenses, and early site permits under part 52, § 50.92 is revised to explicitly refer to these part 52 licenses to eliminate any confusion with respect to the applicability of this section to part 52 licenses. A similar change is made in the introductory paragraph of § 50.91.

Sections 50.92 and 50.91(a)(4) implement the Commission's authority under Section 189 of the AEA to dispense with the advance publication of a *Federal Register* document requesting a hearing with respect to license amendments, and to make operating license and combined license amendments immediately effective upon issuance, if the NRC finds that the amendment involves no significant hazards consideration. The NRC is revising § 50.92(c) to clarify that, consistent with Section 189 of the AEA, the NRC may make a no significant hazards consideration determination for amendments of combined licenses under

part 52. Combined licenses are explicitly mentioned in Section 189.a.(2)(A) of the AEA with respect to immediate effectiveness following a Commission determination of a no significant hazards consideration. In addition, a combined license merges into a single license the authority otherwise contained in a construction permit and an operating license, and the language of Section 189.a.(1)(A) of the AEA which refers to both amendments of construction permits and operating licenses, also applies to amendments of combined licenses.

Finally, § 50.92(a) is revised to provide that a separate application for a construction permit is not required even where a holder of a combined license or a manufacturing license must seek a license amendment because of a material alteration. There is no safety or regulatory benefit in requiring the licensee to concurrently submit an application for a new construction permit in addition to a license amendment, inasmuch as NRC review of the alteration is assured.

10. Revocation, Suspension, Modification, Amendment of Licenses and Construction Permits, Emergency Operations by the Commission.

a. Section 50.100, *Revocation, suspension, modification of licenses, permits, and approvals for cause.*

Section 50.100 is revised to explicitly address the Commission's authority to suspend, modify, or revoke any standard design approval under subpart E of parts 50 or 52 for any material false statement in the application, or because of any statement in any report, record, inspection, or condition revealed by the application, or by other means, which would warrant the NRC to refuse to grant the design approval on an original application. The former language of

§ 50.100, which is retained as paragraph (a) in the final rule, applied to any license or any license or construction permit issued under part 50 for any material false statement in the application for the license or permit, or because of any statement in any report, record, inspection, or condition revealed by the application, or by other means, which would warrant the NRC to refuse to grant a license on an original application, or for failure to construct or operate a facility in accordance with the applicable license or permit. While this language applies to early site permits, combined licenses and manufacturing licenses, by virtue of their status as licenses under the AEA, it does not clearly apply to standard design approvals as these are not licenses. Nonetheless, the Commission possesses authority to modify, suspend or revoke the regulatory approvals. Accordingly, the NRC is revising this section to add a reference to a standard design approval.

The final rule is different than the proposed rule in several ways. A reference to part 50 is added in the clause governing revocations, suspensions, and modifications of licenses. The word, “provided...,” is revised to read, “provided, however,....” Finally, a reference to a combined license is added to the clause stating that a failure to meet the timely completion of proposed construction or alteration is subject to § 50.55(b) (which is also revised in this final rulemaking to make its provisions applicable to combined licenses).

11. Backfitting.

a. Section 50.109, *Backfitting*.

The backfit rule, 10 CFR 50.109, provides certain protection to nuclear power plant licensees against changes in the NRC requirements and NRC staff positions on those requirements. Prior to the final rule, the backfitting provisions in § 50.109 applied to standard

design approvals, construction permits, and operating licenses, but did not address combined licenses or manufacturing licenses. Part 52 contains special backfitting requirements on early site permits, design certification rules, but prior to this rulemaking, neither § 50.109 or part 52 addressed backfitting of a combined license, although the NRC recognizes that backfitting restraints for an early site permit and a design certification rule would apply to a combined license referencing either or both. To address these gaps in backfitting, and to clarify the application of special backfitting provisions, § 50.109(a)(1) is revised by establishing the date that backfitting protection begins for a manufacturing license, a construction permit for a duplicate design license, and a combined license. Moreover, with respect to a part 50 construction permit, a part 50 operating license, and a part 52 combined license, § 50.109 is revised by listing the specific backfitting restrictions that apply if an early site permit, standard design approval, or standard design certification rule is referenced, or if a nuclear power reactor manufactured under a part 52 manufacturing license is used.

In the statement of considerations for the 2006 proposed rule, the Commission asked whether, instead of conforming the language of § 50.109 to reflect the licensing and regulatory approval processes in part 52, the Commission should adopt a general backfitting provision, analogous to § 50.109, in part 52. Commenters either expressed no opinion on the matter, or otherwise indicated that they did not have a preference. Accordingly, the Commission has decided to revise § 50.109 to include the conforming changes, rather than adopting a backfitting provision in part 52.

12. Enforcement.

a. Section 50.120, *Training and qualification of nuclear power plant personnel.*

This section sets forth the requirements for training and qualifying nuclear power plant personnel. In a conforming change, the NRC is revising § 50.120 to add applicants for and holders of combined licenses as being subject to this provision.

13. Appendices.

a. APPENDIX A TO PART 50 – GENERAL DESIGN CRITERIA FOR NUCLEAR POWER PLANTS.

The first paragraph of the Introduction to appendix A to part 50 is revised to clarify that the general design criteria in appendix A to part 50 apply to applications for combined licenses, design approvals, design certification, and manufacturing licenses, as well as for construction permits. Also, General Design Criterion (GDC) 19 of appendix A to part 50, which sets forth requirements for a main control room in a nuclear power plant, is revised to clarify that the radiation protection requirements in GDC 19 for applications filed after January 10, 1997, apply to design approvals and manufacturing licenses issued under part 52, in addition to design certifications and combined licenses.

b. APPENDIX B TO PART 50 – QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANTS AND FUEL REPROCESSING PLANTS.

Appendix B to part 50 states that every applicant for a construction permit is required to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility and

every applicant for an operating license is required to include, in its FSAR, information pertaining to the managerial and administrative controls to be used to assure safe operation. The NRC is revising appendix B to part 50 to clarify that these requirements also apply to early site permits, design approvals, design certifications, combined licenses, and manufacturing licenses under 10 CFR part 52. Specifically, the introduction to appendix B to part 50 is revised to state that every applicant for a combined license is required by the provisions of § 52.79 to include in its FSAR a description of the quality assurance program applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operation. The introduction also states that, for applications submitted after the effective date of the final rule, every applicant for an early site permit is required by the provisions of § 52.17 to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site. The introduction states that every applicant for a design approval or design certification is required by the provisions of §§ 52.137 and 52.47, respectively, to include in its FSAR a description of the quality assurance program applied to the design of the SSCs of the facility. Finally, the introduction states that every applicant for a manufacturing license is required by the provisions of 10 CFR 52.157 to include in its FSAR a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the SSCs of the reactor. The wording in appendix B of part 50 and in the related provisions in the contents of application sections in 10 CFR part 52 is modified slightly in the final rule to reflect that some activities have already occurred when the application is submitted (e.g., design of SSCs for design certification applicants). Therefore, instead of requiring that the application describe the QA program “to be applied” to these activities, the

final rule requires that the application describe the QA program “applied” to these activities, since they have already occurred.

The NRC is maintaining the current regulatory structure for requirements that implement appendix B to part 50 whereby QA for construction activities is governed by § 50.55(f), and QA for operation is governed by § 50.54(a). Because a combined license under part 52 authorizes both construction and operation, a combined license holder should be subject to the QA requirements in § 50.55(f) from the date of issuance of the combined license until the Commission makes the finding under § 52.103(g) that allows the licensee to load fuel and operate. Thereafter, the combined license holder should be governed by the QA requirements in § 50.54(a). The manufacture of a nuclear power reactor under a manufacturing license is the functional equivalent of construction. Accordingly, the NRC is revising § 50.55(f) to refer to holders of manufacturing licenses under part 52. Early site permits under subpart A precede construction and are considered partial construction permits. Hence the NRC believes that they should be subject to QA under § 50.55(f), and § 50.55(f) is revised accordingly.

Appendix B to part 50 was formerly applicable to combined licenses under the provisions of § 52.83, which states that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses. Appendix B to part 50 formerly applied to design certifications by virtue of the provision in former § 52.48, which stated that design certification applications will be reviewed for compliance with the standards set out in 10 CFR part 50 as they apply to applications for construction permits and operating licenses for nuclear power plants, and as those standards are technically relevant to the design proposed for the facility. Former appendix O to part 52, Section O.3, required applicants for design approvals to include the information required by §§ 50.34(a) and (b), as appropriate, and stated that the information required by § 50.34(a)(7) (a description of the quality assurance program and a discussion of how the applicable

requirements of appendix B to part 50 will be satisfied), shall be limited to the QA program to be applied to the design, procurement and fabrication of the SSCs for which design review has been requested. Appendix B to part 50 formerly applied to manufacturing licenses by virtue of the provision in former appendix M to part 52, Section M.1, which stated that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses.

Early site permits are considered partial construction permits, therefore, the NRC believes that they should be subject to the QA requirements of appendix B to part 50. Section 52.39, with certain specific exceptions, requires the Commission to treat matters resolved in an early site permit proceeding as resolved in making findings for issuance of a construction permit, operating license, or combined license. Because of this finality, conclusions made during the early site permit phase will be relied upon for use in subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an early site permit is issued. Therefore, the NRC believes that the level of quality used to control activities related to safety-related SSCs should be equivalent in the early site permit and combined license phases. For these reasons, applicants must apply quality controls to each early site permit activity associated with the generation of design information for safety-related SSCs that meet the criteria in appendix B to part 50. Therefore, the NRC is revising appendix B to part 50 to make it applicable to early site permits.

c. APPENDIX C TO PART 50 – A GUIDE FOR THE FINANCIAL DATA AND RELATED INFORMATION REQUIRED TO ESTABLISH FINANCIAL QUALIFICATIONS FOR CONSTRUCTION PERMITS AND COMBINED LICENSES.

Section 182.a of the AEA requires an applicant for a license for a production or utilization facility to submit information in its application... “as the Commission, regulation, may determine to be necessary to decide such of the technical and financial qualifications of the applicant...as the Commission may deem appropriate for the license.” The NRC has long determined the need for non-utility applicants for nuclear power plant construction permits and operating licenses to establish their financial qualifications (see 10 CFR 50.33(f)), and has set forth the specific information on financial qualifications to be provided by applicants for construction permits in appendix C to part 50. Inasmuch as holders of combined licenses under part 52 are authorized to perform the same construction activities with respect to a nuclear power plant as a holder of a construction permit under part 50, the NRC believes that applicants for combined licenses should be subject to the requirements of appendix C to part 50. Accordingly, the title of appendix C is revised to make clear the applicability of this appendix to applicants for combined licenses. This change constitutes a conforming change to the revision of § 50.33.

With the exception of manufacturing licenses, none of the other regulatory processes under part 52, *e.g.*, early site permits, standard design certifications, and standard design approvals, authorize any activities constituting “construction” under the AEA and the Commission’s regulations.⁵ Therefore, the final rule does not refer to early site permits, design certifications, or design approvals under part 52. With respect to a reactor manufacturing license, the NRC does not believe that a financial qualifications review is necessary for several reasons. A financial qualifications review at the manufacturing license stage would appear to

⁵Although early site permit applicants may seek the authority to conduct activities allowed under 10 CFR 50.10(e)(1) (but not activities allowed under § 50.10(e)(3), see § 52.17(c)), these activities are not considered “construction.”

be redundant to the financial qualifications review that is already necessary at the construction permit and operating license stages, or combined license stage. Sufficient safety and quality assurance reviews, including the use of ITAAC in the case of a combined license, should be sufficient to address any adverse impacts on safety as the result of inadequate financial resources to properly manufacture the reactor. Furthermore, the NRC notes that manufacture of a reactor is, in many respects, no different than fabrication of components and systems by third party vendors, who are not required to obtain an NRC license and demonstrate financial qualifications. There seems to be no regulatory value to mandate a financial qualifications review of manufacturing license applicants, when this type of review is conducted by the NRC for fabricators of nuclear power plant systems and components.

d. APPENDIX E TO PART 50 – EMERGENCY PLANNING AND PREPAREDNESS FOR PRODUCTION AND UTILIZATION FACILITIES.

See discussion in Section V.D.4.f of this document.

e. APPENDIX I TO PART 50—NUMERICAL GUIDES FOR DESIGN OBJECTIVES AND LIMITING CONDITIONS FOR OPERATION TO MEET THE CRITERION “AS LOW AS IS REASONABLY ACHIEVABLE” FOR RADIOACTIVE MATERIAL IN LIGHT-WATER-COOLED NUCLEAR POWER REACTOR EFFLUENTS.

The Commission is revising appendix I to part 50 to conform to the changes in §§ 50.34a and 50.36a which are being made as part of this final rule. Specifically, a statement is added in Section I of appendix I to part 50, stating that §§ 52.47, 52.79, 52.137, and 52.157

provide that applications for design certification, combined license, design approval, or manufacturing license, respectively, shall include a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems. In addition, Section II of appendix I to part 50 is revised to state that the guides on design objectives set forth in appendix I to part 50 may be used by an applicant for a combined license as guidance in meeting the requirements of § 50.34a(d) or by an applicant for a design approval, a design certification, or a manufacturing license as guidance in meeting the requirements of § 50.34a(e). Section IV of appendix I to part 50 is revised to state that the guides on limiting conditions for operation for light-water-cooled nuclear power reactors in appendix I to part 50 may be used by an applicant for an operating license or a design certification or combined license, or a licensee who has submitted a certification of permanent cessation of operations under § 50.82(a)(1) or § 52.110 as guidance in developing technical specifications under § 50.36a(a) to keep levels of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable. Finally, Section V of appendix I to part 50 is revised to state that the guides for limiting conditions for operation set forth in appendix I are applicable to any application filed on or after January 2, 1971, for a construction permit for a light-water-cooled nuclear power reactor, or a design certification, a combined license, or a manufacturing license for a light-water-cooled nuclear power reactor under part 52. Note that the NRC added the phrase “for a light-water-cooled nuclear power reactor” to Section V in the final rule. This phrase was inadvertently left out of the introduction to Section V in the proposed rule. The NRC did not intend to change the applicability of appendix I in this rulemaking and is, therefore, correcting this omission in the final rule. The NRC has also removed the conforming change it had proposed to paragraph A.3 of the Concluding Statement of Position of the Regulatory Staff (Docket–RM–50–2) Guides on Design Objectives for Light-Water-Cooled Nuclear Power Reactors in appendix I. The design

objectives in this staff position are only applicable to those light-water-cooled nuclear power reactors that applied for a construction permit before January 2, 1971 (per Appendix I, Section V, B.2.). Because part 52 did not exist before 1971, the proposed change is unnecessary.

f. APPENDIX J TO PART 50 – PRIMARY REACTOR CONTAINMENT LEAKAGE TESTING FOR WATER-COOLED POWER REACTORS.

Section 50.54(o) provides a condition for all operating licenses for water-cooled power reactors that primary reactor containments must meet the containment leakage test requirements set forth in appendix J to part 50. These test requirements provide for preoperational and periodic verification by test of the leak-tight integrity of the primary reactor containment, and systems and components which penetrate containment of water-cooled power reactors, and establish the acceptance criteria for these tests. The purpose of the tests are to assure that leakage through the primary reactor containment systems and components penetrating primary containment shall not exceed allowable leakage rate values as specified in the technical specifications or associated bases, and periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment. The Commission is revising appendix J to clarify that these requirements also apply to combined licenses under 10 CFR part 52. This is consistent with former § 52.83, which stated that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses.

g. APPENDICES M AND O TO PART 50 [Removed].

The NRC has removed appendices M and O from 10 CFR part 50. Appendix M provided for issuance of a license authorizing the manufacture of a nuclear power reactor to be incorporated into a nuclear power plant under a construction permit and operated under an operating license at a different location from the place of manufacture. Appendix O addressed the early review of site suitability issues. These appendices were transferred to 10 CFR part 52 when it was first issued (54 FR 15372; April 18, 1989). However, the NRC failed to remove those appendices from 10 CFR part 50, though the NRC intended to do so (see 54 FR 15385; April 18, 1989).

h. APPENDIX S TO PART 50 – EARTHQUAKE ENGINEERING CRITERIA FOR NUCLEAR POWER PLANTS.

Appendix S to part 50 provides earthquake engineering criteria for nuclear power plants and applies to applicants for a design certification or combined license under part 52 or a construction permit or operating license under part 50. The final rule revises appendix S to clarify that the requirements in appendix S also apply to applicants for design approvals and manufacturing licenses issued under 10 CFR part 52. Although former appendix O to part 52 did not explicitly require applicants for design approvals to comply with the requirements of appendix S, the NRC is requiring design approval holders to comply with appendix S to part 50 because the NRC believes that the requirements for a design approval should be the same as the requirements for a design certification, given that the reviews performed by the NRC staff for the two products are essentially identical. Finally, appendix S formerly applied to

manufacturing licenses by virtue of former appendix M to part 52, Section M.1, which stated that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses. Therefore, the Commission is revising the General Information section of appendix S to part 50 to state that the appendix applies to applicants for a design certification, design approval, combined license, or manufacturing license under 10 CFR part 52 or a construction permit or operating license under 10 CFR part 50. The NRC also made conforming changes to the Introduction, paragraph (a) to appendix S to part 50, and added definitions for *design approval* and *manufacturing license* to Section III of appendix S to part 50, to be consistent with the definitions in proposed part 52.

E. Change to 10 CFR Part 1.

1. Section 1.43, *Office of Nuclear Reactor Regulation*.

Section 1.43 describes the responsibilities of the Office of Nuclear Reactor Regulation (NRR), which includes the development and implementation of regulations, policies, programs and procedures for the receipt, possession or ownership of source, byproduct and special nuclear material that is used or produced at nuclear power plants. Inasmuch as power plants may be licensed under part 52 as well as part 50, § 1.43(a)(2) is revised to clarify that NRR has authority over the development and implementation of regulations, policies, programs and procedures for the receipt, possession or ownership of source, byproduct and special nuclear material that is used or produced at nuclear power plants licensed under part 52. In addition, a correction has been made to reference part 54, to clarify that NRR has the same authority with respect to renewed operating licenses for nuclear power plants.

F. Changes to 10 CFR Part 2.

1. Section 2.1, Scope.

The statement of scope for part 2 is revised by adding a reference to rulemaking and standard design approvals. Previously, the scope statement did not mention rulemakings, even though subpart H of part 2 applied to rulemakings, nor did it mention standard design approvals even though the NRC processed applications for design approvals in accordance with the procedures in part 2. Accordingly, the change in the statement of scope for part 2 correctly reflects the applicability of its procedures to both rulemaking and the processing of standard design approvals.

2. Section 2.4, Definitions.

The definitions of *contested proceeding*, *license*, and *licensee*, are revised in part 2 by adding conforming references, as appropriate, to the licensing processes in part 52. The revised definition of *contested proceeding* clarifies that contested proceedings include those involving permits, such as early site permits and construction permits. The revised definition of *license*, ensures that early site permits and construction permits, as well as part 52 combined licenses and manufacturing licenses, are considered to be licenses for purposes of part 2. Similarly, the revised definition of *licensee* ensures that holders of early site permits and construction permits, as well as combined licenses and manufacturing licenses, are considered to be licensees for purposes of part 2.

3. Section 2.100, *Scope of subpart.*

This section is revised by adding conforming references to issuance of a standard design approval under subpart E of part 52.

4. Section 2.101, *Filing of application.*

This section, which governs the procedures for, and the timing and content of applications, has been revised in several respects. Paragraphs (a)(1), (a)(2), the introductory paragraph of (a)(3), paragraph (a)(3)(iii), and paragraph (a)(4) are revised by adding conforming references to combined licenses, early site permits, and standard design approvals. The Commission notes that the former language of § 2.101 already applied to combined licenses, as well as early site permits, inasmuch as they are both licenses. Nonetheless, consistent with the revisions to the definitions of *license* and *licensee*, § 2.101 has been revised to explicitly refer to early site permits, as applicable.

In response to public comment on the proposed rule, paragraph (a)(5) of § 2.101 and paragraph (a-1) are revised to allow applicants for combined licenses - as well as applicants for construction permits as provided under this section - to submit applications in parts. Paragraph (a)(5) of the final rule allow applicants for combined licenses and construction permits to submit an application in two parts, with one part containing the environmental report required under § 50.30(f) if the application is for a construction permit or § 52.80(c) if the application is for a combined license. The other part must contain the information required by §§ 50.34(a) and 50.34a if the application is for a construction permit, or § 52.79 and § 52.80(a) and (b) if the application is for a combined license. In addition, the part that is filed first must contain the information required by § 50.33, § 50.34(a)(1) if the application is for a construction

permit, § 52.79(a)(1) if the application is for a combined license, and § 50.37. There are no considerations unique to combined licenses which would weigh against allowing a combined license applicant to submit a two part application under paragraph (a)(5) of § 2.101.

Accordingly, the Commission is adopting this change in the final rulemaking. Inasmuch as the revisions are to the Commission's rules of procedure and practice, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

Paragraph (a-1) of § 2.101 allows applicants for combined licenses, as well as applicants for construction permits, to submit an application in parts to allow for early consideration and a presiding officer's partial initial decision on those site suitability matters for which the applicant seeks NRC resolution. The provisions governing early consideration of site suitability issues in a combined license proceeding are set forth in paragraph (a-1)(2). Under this paragraph, a combined license application may be submitted in three parts, with the first part containing information on the site suitability issues which the applicant wishes to have resolved first. The second and third parts, which constitute the remainder of the application as described in paragraph (a-1)(2)(ii) and (iii), must be submitted during the period that the partial decision on part one is effective, viz., 5 years under new § 2.627 in subpart F of part 2. There are no considerations unique to combined licenses which would weigh against allowing a combined license applicant to obtain early consideration of site suitability issued under paragraph (a-1). As with the change to paragraph (a)(5), this revision to paragraph (a-1) constitutes revisions to the Commission's rules of procedure and practice. Accordingly, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

5. Section 2.102, *Administrative review of application.*

This section is revised by adding conforming references in § 2.102(a) to applications for early site permits, standard design approvals, combined licenses, and manufacturing licenses under part 52. Under the revised section, the NRC staff will establish a review schedule for an application for these processes, thereby treating the applications the same as applications for construction permits or operating licenses.

6. Section 2.104, *Notice of hearing.*

Section 2.104 sets forth the Commission's requirements regarding publication in the *Federal Register* of notice of hearings. Paragraph (a), which sets forth general requirements regarding the content of such notices, is revised by adding conforming references to a combined license and early site permit, to indicate that the NRC will provide at least 30 days notice in the *Federal Register* of a hearing.

Formerly, paragraph (b) established the minimum content of the notice of (mandatory) hearing for a construction permit, and paragraph (c) established the minimum content of the notice of opportunity for hearing for an operating license under part 50. However, § 2.104 did not address the content of notices of hearings for part 52 processes. The NRC believes that there is some benefit, in terms of public transparency and regulatory efficiency and consistency, in establishing the minimum content for notices of hearing for part 52 licensing processes. Therefore, § 2.104 is revised to address the minimum content of the notice of hearing for part 52 processes. Former paragraph (d) is redesignated as paragraph (l), and former paragraph (e) is redesignated as paragraph (m). New paragraphs (d) is added to establish the content of notices of hearing involving applications for early site permits, and new paragraphs (e) and (f) are added to address the content of notices involving applications for combined licenses not referencing an early site permit, and combined licenses referencing an

early site permit. Each of these paragraphs is modeled on the notice of hearing for construction permit, but modified to reflect the criteria for determining the application, as reflected in §§ 52.24, 52.97, and 52.167, for early site permits, combined licenses, and manufacturing licenses, respectively.

Paragraphs (e)(1) is further revised in the final rule to clarify that it applies only with respect to contested matters (*i.e.*, matters which are the subject of admitted contentions). A new paragraph (e)(2) is added to specify that in a contested combined license proceeding, the scope of the presiding officer's findings and conclusions of law for uncontested matters is limited to issues which are otherwise required to be addressed in a construction permit proceeding. Proposed paragraph (e)(2) is redesignated as paragraph (e)(3) in the final rule, and is revised to specify that in an uncontested combined license proceeding (*i.e.*, where there are no interveners and no contentions), the scope of the presiding officer's findings and conclusions of law is limited to issues which are otherwise required to be addressed in a construction permit proceeding. A new paragraph (f) is added to clearly state that if the combined license references an early site permit, then the presiding officer's consideration of uncontested matters extends only to those uncontested matters otherwise required to be addressed in a construction permit proceeding, but which have not been addressed in the referenced early site permit proceeding. The NRC notes that §§ 2.104(e) and (f) apply to both contested and uncontested combined license proceedings. Hence, in an uncontested combined license proceeding, the presiding officer's initial decision is limited to those matters which would otherwise required to be addressed in a construction permit proceeding. Furthermore, if that uncontested combined license references an early site permit, then the presiding officer's initial decision is further constrained to address only those construction permit matters which have not been addressed and resolved in the referenced early site permit proceeding.

Paragraph (f) in the March 2006 proposed rule, which would have required publication of a notice of a “mandatory” hearing for manufacturing licenses under subpart F of part 52, is deleted in the final rule. A manufacturing license does not, *per se*, authorize construction of a nuclear power plant. Therefore, a statutory hearing for a manufacturing license is not required under Section 189.a.(1)(A) of the AEA, which applies only to issuances of construction permits. Furthermore, adjudicatory hearings may not be the best approach for resolving technical design issues - especially in uncontested proceedings. Indeed, the NRC removed the opportunity for adjudicatory-style hearings for design certifications as part of the 2004 changes to 10 CFR part 2 (January 14, 2004; 69 FR 2182). The primary responsibility for determining the safety of an application is with the NRC staff, and not the presiding officer. This is true regardless of whether the proceeding is contested or uncontested. Public confidence would not seem to be enhanced in any significant manner by the holding of a hearing where there is no request that the NRC hold a hearing. Accordingly, the NRC has decided not to adopt in the final Part 52 rule a requirement for a “mandatory” hearing in connection with issuance of manufacturing licenses.

Paragraph (m) (formerly paragraph (e)) requires the NRC to transmit a notice of a hearing on an initial application of a license for a production or utilization facility to an appropriate State official and the chief executive of the municipality or county in which the facility is to be located or an activity is to be conducted. In addition to the redesignation, § 2.104(m)(1) is revised to clarify that the notice would be provided for applications for early site permits, combined licenses, but not for manufacturing licenses. Manufacturing licenses are excluded from the notification provisions because the NRC is not licensing any particular location or site where manufacturing may occur (see discussion of the manufacturing license concept).

7. Section 2.105, *Notice of proposed action.*

Section 2.105 contains the NRC's procedures for notices of proposed actions where a hearing is not required by law and if the Commission has determined that a hearing is in the public interest. Inasmuch as amendments to combined licenses and manufacturing licenses do not require a mandatory hearing under the AEA, § 2.105(a)(4) is revised to clarify that the procedures in § 2.105 also apply to applications for amendments of combined licenses and manufacturing licenses. Furthermore, because the AEA does not require a mandatory hearing for the initial issuance of manufacturing licenses, paragraph (a)(13) is added in the final rule to provide for publication of a notice of proposed action in connection with an application for a manufacturing license under subpart F of part 52.

Under § 52.103(a), which implements Section 189.a(1)(B)(i) of the AEA, the NRC is required to publish in the *Federal Register* a notice of intended operation and an opportunity to request a hearing with respect to compliance of the facility with inspections, tests, and acceptance criteria in a part 52 combined license. Accordingly, the NRC is revising § 2.105 by adding § 2.105(a)(12) which addresses the information to be contained in the *Federal Register* notice required by § 52.103(a).

Because the Commission's authorization for a combined license holder to operate under § 52.103 does not constitute "issuance" of a license or amendment under § 2.106, § 2.105(b)(3) is added indicating that the Commission will publish a notice of intended operation in the *Federal Register* that identifies the proposed Agency action as making the finding under § 52.103(g). Paragraph (b)(3)(iii) of the proposed rule, which would have required that the Commission publish, as part of that *Federal Register* notice, a finding that ITAAC have been met, has not been included in the final rule. This is because Commission may not have made, at the time of the *Federal Register* notice, the finding that all ITAAC have been met. After careful review of the language of Section 189 of the AEA, the Commission concludes that the *Federal Register* notice required by Section 189.a(1)(B)(i) need not include a finding that ITAAC

have been met. Accordingly, § 2.105(b)(3) of the final rule does not include a requirement for such a finding to be included in the *Federal Register* notice of intended operation.

8. Section 2.106, Notice of issuance.

Section 2.106(a) formerly provided that the NRC will publish in the *Federal Register* a notice of issuance of a license or amendment of a license where a notice of proposed action has been previously published, and notice of amendment of a nuclear power plant license. However, that language did not require publication in the *Federal Register* that the Commission has made the finding under § 52.103(g). Although the AEA does not require publication of a notice of the Commission finding under § 52.103, the Commission believes that this publication is desirable as a matter of public transparency and consistency with past practice of the *Federal Register* publication of Commission action with similar effects (*i.e.*, the issuance of a nuclear power plant operating license). Accordingly, § 2.106(a) is revised to require *Federal Register* publication of the Commission finding under § 52.103.

Section 2.106(b)(2) is also revised to set forth the minimum requirements for the contents of a *Federal Register* notice of action, *e.g.*, the manner in which copies of the safety analyses, if any, may be obtained and examined, and a finding that the prescribed inspections, tests, and analyses have been performed and that the acceptance criteria prescribed in the combined license have been met, and that the license complies with the requirements of the AEA and the NRC's regulations. These provisions are the same as the existing requirements with respect to notices of issuance for licenses and license amendments, but adds the requirements with respect to ITAAC mandated by Section 185 of the AEA and part 52. The NRC disagrees with the contention raised by the nuclear industry that Section 185 of the AEA limits the NRC to a finding of compliance with respect to ITAAC under § 52.103(g). Nothing in

the legislative history suggests that by adopting Section 185 of the AEA, Congress intended to override the NRC's long-standing practice of making findings of compliance with the Act and the Commission regulations when issuing nuclear power plant licenses.

9. Section 2.109, *Effect of timely renewal application.*

Section 2.109 is revised to add conforming references to a combined license under subpart C of part 52. The revised language clarifies that an application for a combined license filed no later than 5 years before its expiration will not be deemed to have expired until the renewal application has been finally determined.

10. Section 2.110, *Filing and administrative action on submittals for standard design approval or early review of site suitability issues.*

In a conforming change, paragraphs (a) and (b) of § 2.110 are revised to refer to subpart E of part 52 and appendix Q of part 50. Paragraph (c) is corrected by adding § 2.110(c)(2) to address the procedures applicable to administrative determinations of submittals for early review of site suitability issues; formerly, paragraph (c) only refers to standard designs.

11. Section 2.111, *Prohibition of sex discrimination.*

This section prohibits sex discrimination against certain persons with respect to, *inter alia*, a license under the AEA. This section is revised to include standard design approvals

under part 52, and petitions for rulemaking, including an application for a design certification under part 52.

12. Section 2.202, *Orders.*

This section is revised by redesignating § 2.202(e) as § 2.202(e)(1), and adding §§ 2.202(e)(2) through (5), to indicate the backfitting provisions in part 52 applicable to the various licensing processes under part 52. No provisions were deemed necessary to address issuance of orders representing backfitting of NRC approvals such as standard design approvals. These approvals, by themselves, do not authorize third party action. Therefore, any agency action to condition their use would not require an NRC order to the holder of a standard design approval.

13. Section 2.340, *Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits, and licenses.*

Section 2.340 addresses several different matters relating to the presiding officer's initial decision and its effect. The final rule reorganizes the paragraphs in this section in order to better distinguish among these matters, reserves paragraphs (g) and (h) for future use by the Commission, and makes substantial changes to these matters addressed in this section, as discussed below. These changes are to the Commission's rules of procedure and practice, and the Commission is adopting the changes in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 5, 553(b)(A).

Scope of presiding officer's initial decision.

Formerly, paragraph (a) limited the scope of the presiding officer's findings and conclusions of law in initial decisions in contested proceedings for production or utilization facility operating licenses to matters put into controversy by the parties. Matters not put into controversy by the parties could only be examined by the presiding officer by direction of the Commission, either on its own initiative or upon the presiding officer's referral of the matter to the Commission. In a conforming change, a new paragraph (b) is added to apply the limitation in contested hearings under § 52.103(g) with respect to whether the acceptance criteria in a combined license ITAAC have been, or will be met.

The § 2.340(a) limitation did not apply to a contested utilization facility construction permit proceeding. Although the statement of considerations for the original rulemaking adopting this limitation (in former § 2.760a) does not directly address the basis for this limitation (see January 17, 1975; 40 FR 2973), the underlying rationale may be gleaned from the Commission's order in *Consolidated Edison Co. of New York* (Indian Point Nuclear Generating Unit 3), 8 AEC 7 (1974) which engendered the rulemaking. In explaining that the Licensing Board has no obligation at the operating license stage to inquire into matters which parties have not raised and the Licensing Board itself has no reason to inquire, the Commission stated:

To have a Licensing Board engage in an idle exercise examining issues just for the sake of examination - when the parties have not raised such matters, and the Board is satisfied that there is nothing to inquire about - would serve no useful purpose. This is particularly true since an operating license proceeding is not to be used to rehash issues already well ventilated and resolved at the

construction permit stage. *Alabama Power Co.* (Joseph M. Farley Nuclear Plant, Units 1 and 2), CLI-74-12 (RAI-74-3-203).

Id. at 8. Thus, the limitation was based, in part, upon the broader scope of inquiry for the presiding officer at construction permit stage, which is a “mandatory hearing” required by Section 189.a(1)(A). This rationale continues to apply today, and consequently the NRC does not propose to alter the NRC’s practice by extending the § 2.340(a)/§ 2.760a limitation to construction permit (including early site permit) proceedings. Nor should the § 2.340(a)/§ 2.760a limitation apply in a part 52 combined license proceeding with respect to matters that would otherwise be addressed and resolved in a construction permit issuance proceeding.

The final part 52 rule includes several changes to implement the NRC’s conclusions in this regard. Section 2.340(a) is revised to provide that the presiding officer in a contested operating license proceeding shall make findings of fact and conclusions of law to, *inter alia*, those matters for which § 2.104 specifies a presiding officer must determine. Paragraphs (b), (c), and (d) are revised to address the scope of the presiding officer’s initial decision in a combined license proceeding (including a renewal or amendment proceeding), in a proceeding under § 52.103(g), and in a manufacturing license proceeding (including a renewal or amendment proceeding).

As discussed previously, the former § 2.340(a)/§ 2.760a limitation applied only to operating license proceedings, and did not apply to other contested proceedings which do not require a “mandatory hearing,” which includes most materials licensing proceedings (with the notable exception of the licensing of a uranium enrichment facility). The statement of consideration in this document merely states that the rule codifies the Commission’s *Indian Point* decision. (see January 17, 1975; 40 FR 2973 (first column)). Inasmuch as the *Indian Point* proceeding involved a utilization facility license, it is likely that the Commission simply did

not consider as part of the rulemaking the possibility of applying the limitation to non-production or utilization facility proceedings, as opposed to making a deliberate decision not to apply the limitation to non-production or utilization facility proceedings. Currently, the NRC believes that with 30 additional years of hearing experience, there is no practical, compelling policy-based, or legal reason why the § 2.340(a) limitation should not be extended to non-production or utilization facility proceedings. Accordingly, the NRC is revising § 2.340 by adding a new paragraph (c), which extends the existing limitation on the presiding officer's initial decision in contested proceedings to all other proceedings not covered by paragraphs (a) or (b) of § 2.340. Although this change is not related to the part 52 rulemaking effort, the NRC is adopting this change as part of the part 52 final rule to ensure that stakeholders understand the provisions of § 2.340 as an integrated whole.

Immediate effectiveness of presiding officer's initial decision in production and utilization facility proceedings.

The remainder of former § 2.340 was an amalgam of the Commission's original rule (10 CFR 2.764⁶) providing that a presiding officer's initial decision in certain proceedings was immediately effective upon issuance, combined with newer provisions - first adopted in 1979 and modified in 1981 - which suspended the immediate effectiveness rule. The "automatic stay" provisions were adopted following the accident at TMI-2, in order to provide for the Commission's direct involvement in the issuance of nuclear power plant licenses. The Commission first issued an *Interim Statement of Policy and Procedure* in October 1979, which first noted that the TMI-2 accident was being investigated by the NRC and may result in

⁶31 FR 12774 (September 30, 1966).

“significant changes in the Commission’s regulatory policy and in the procedures it employs to license nuclear power facilities.” The Policy Statement then indicated that “new construction permits, limited work authorizations, or operating licenses for any nuclear power plants shall be issued only after action of the Commission itself.” (See October 10, 1979; 44 FR 58559.) Soon thereafter, on November 9, 1979 (44 FR 65049), the NRC issued a *Suspension of § 2.764 and Statement of Policy on the Conduct of Adjudicatory Proceedings*. As part of this final rulemaking, the NRC adopted a new appendix B to part 2 addressing the suspension of immediate effectiveness provisions in § 2.764, and providing for both Atomic Safety and Licensing Appeal Board review and Commission review of the presiding officer’s initial decision.

On May 28, 1981 (46 FR 28627), the NRC issued a final rule which removed the need for the Appeal Board review of a presiding officer’s initial decision, but retained a minimum 60-day period for Commission review. The final rule was almost immediately amended to exclude from Commission review presiding officer decisions authorizing fuel load and low-power testing (September 30, 1981; 46 FR 47764). In 2004, the provisions in § 2.764 were transferred without substantive change to a new § 2.340 as part of the general revision to 10 CFR part 2 (January 14, 2004; 69 FR 2182).

While the NRC’s 1979 and 1981 rulemakings were justified in light of the circumstances at that time, other factors now lead the NRC to believe that the oversight provisions adopted in 1981 are no longer necessary or desirable in 2006. In the 25 years since the adoption of the 1981 provisions, the NRC’s regulatory framework and requirements for nuclear power plants has evolved and strengthened. The NRC’s technical requirements for nuclear power reactors were substantially augmented in the years immediately following the TMI accident, and thereafter have evolved to reflect lessons learned, new information, and the increasing acceptance of risk-informed methodologies. Similarly, the NRC’s oversight of nuclear power plants has evolved to reflect lessons learned, new information, and the maturation of risk

assessment methodologies. Thus, the NRC believes it's regulations may be revised to remove the regulatory requirement for direct Commission involvement in all production and utilization licensing proceedings. The Commission's words in the May 1981 final rulemaking apply with more force today:

This amendment does not compromise the Commission's commitment to the protection of public health and safety or to a fair hearing process. Thorough technical safety reviews of license applications by the NRC staff and the Advisory Committee on Reactor Safeguards, the availability of public hearings on license applications, and the Commission's inherent supervisory authority form the basis of the network of procedural safeguards intended to implement this commitment to a fair decision process and public health and safety. (May 28, 1981; 46 FR 28628 first column)

The NRC's commitment remains unchanged, and the NRC's safeguards have been strengthened since that time, for example, by refocusing the regulatory process to include considerations of risk. In addition, the NRC's rules of practice in part 2 provide several procedural safeguards within the NRC's administrative process, including: (1) a petition for presiding officer reconsideration under § 2.345; (2) a petition for Commission review under § 2.341; and (3) a motion for a stay with the presiding officer or the Commission under § 2.342.

By removing the "automatic stay" provisions in former § 2.340(f) and (g), the NRC's administrative process will be completed in less time, thereby benefitting all parties from the reduction in litigation resources without compromising the fairness of the overall hearing process. Faster completion of the adjudication will also enable aggrieved parties to more quickly seek relief via an appeal to a U.S. Circuit Court of Appeals. The NRC believes that

Congress intends the Commission to conduct fair, but efficient, hearings with respect to licensing, and to remove unnecessary hearing procedures which do not contribute to such a hearing process. This is evidenced by Section 189 of the AEA, as amended by the Energy Policy Act of 1992, which directs the Commission to issue, “to the maximum possible extent,” a final decision on issues raised with respect to acceptance criteria by the anticipated date for initial loading of fuel. The Commission concludes that the changes to § 2.340 are consistent with applicable law, and will provide tangible benefits to all parties in NRC adjudications.

Immediate effectiveness of presiding officer’s initial decision in other, non-production or utilization facility proceedings.

As noted previously, the 1981 final rulemaking provided for an “automatic stay” to provide for direct Commission involvement in the issuance of nuclear power plant licenses. Since that time, the NRC has extended the “automatic stay” provisions in § 2.340 to other licensing contexts, such as independent spent fuel storage facilities (ISFSIs) at sites away from nuclear power reactors, monitored retrievable storage (MRO) licenses, and provided for a parallel provision in 10 CFR part 61 for low-level waste (LLW) facilities, see 10 CFR 2.1211. The NRC did not explain the basis for requiring direct Commission involvement in the issuance of a part 61 LLW license (see 47 FR 57446; December 27, 1982), although one could surmise from the timing of the rulemaking that the factors underlying the 1981 rulemakings also were the basis for the 1982 rulemaking’s provision providing for direct Commission involvement in part 61 license issuances. The NRC’s original intent in requiring direct Commission involvement in the issuance of specific ISFSI licenses and a MRS license was the lack of regulatory experience (see, e.g., 60 FR 20879 and 20883; April 28, 1995), and, therefore, is somewhat different from the motivating factors for the 1981 rulemakings. In any event, the

NRC now has had the benefit of experience in licensing a specific ISFSI, as well as several specific ISFSIs located at reactor sites. Thus, the NRC has come to a recognition that the safety, security and regulatory issues associated with these licenses are of less complexity than those associated with nuclear power plants, and that the NRC has greater time to respond to potentially adverse situations. *Compare* 46 FR 47764, at 47765 (issuance of licenses for activities involving minimal risk to public health and safety, and greater time to take corrective action, do not require Commission involvement). Furthermore, the Commission possesses general supervisory authority over the NRC staff and may direct the staff to keep the Commission apprised of licensing status and issues for such licenses. Accordingly, the NRC concludes that there is little regulatory benefit to be provided by a rule requiring direct Commission involvement in the issuance of these licenses and that the provisions in § 2.340 providing for such involvement should also be removed as part of this streamlining of the regulatory process.

Issuances of authorizations, permits, licenses, and § 52.103(g) findings.

Former paragraph (c) of § 2.340 provided that the appropriate staff Office Director was authorized to issue certain delineated licenses, including license amendments, construction permits, and construction authorizations, within 10 days from the date of issuance of an initial decision. The former language could be erroneously read as *requiring* the Director to issue a license following an initial decision on a contested matter, even if other issues not contested had yet to be resolved by the NRC staff. In addition, paragraph (c) did not address the issuance of a finding under § 52.103(g). To resolve these concerns, new paragraphs (i), (j), and (k) are added to § 2.340. In general, each paragraph authorizes the appropriate staff Office Director to issue the delineated license, permit, authorization or finding within 10 days

from the issuance of an initial decision, if all other safety and environmental findings necessary for issuance of the license, permit, authorization or finding have been made, notwithstanding the pendency of various petitions or motions for reconsideration, review or stay before the presiding officer or the Commission.

Paragraph (i) authorizes the Director of Nuclear Reactor Regulation (NRR) or the Director of the Office of New Reactors (NRO), as appropriate, to issue nuclear power plant licenses, including amendments, permits and authorizations, within 10 days of the initial decision. Paragraph (j) authorizes the Commission or the appropriate staff Office Director to make the finding under 10 CFR 50.103(g) that the acceptance criteria in a combined license have been met. Finally, paragraph (k) addresses the issuance of other licenses that are issued by the Director of Nuclear Material Safety and Safeguards (NMSS). Typical licenses of this type would be materials licenses for, *inter alia*, medical uses, well logging, radiography, irradiators, and research.

14. Section 2.390, *Public inspections, exemptions, requests for withholding.*

Section 2.390 governs the availability of NRC records and documents regarding a license, permit or order, and implements the Freedom of Information Act (FOIA). This section is revised to make clear that its provisions also applies to NRC records and documents regarding standard design approvals under part 52.

15. Subpart D—Additional Procedures Applicable to Proceedings for Issuance of Licenses for Nuclear Power Plants of Identical Design at Multiple Sites.

Formerly, subpart D of part 2 set forth the Commission's administrative and hearing procedures for proceedings for issuance of construction permits and operating licenses under part 52 for nuclear power plants of "duplicate" design at multiple sites. The requirements governing the content of such applications and the technical consideration of such applications are set forth in 10 CFR part 50, appendix N, which was "transferred" to part 52 as part of the 1989 part 52 rulemaking. However, the 1989 rulemaking did not remove appendix N from part 50, nor did the Commission make conforming changes to appendix N in part 52 to make its provisions applicable to combined licenses under subpart C of part 52. As discussed elsewhere, in the March 2006 proposed rule the Commission proposed deleting appendix N in part 52, and retaining these provisions in part 50. Although no comment was received on this proposal, the Commission has decided to withdraw its proposal to delete appendix N in part 52. Instead, the Commission is revising appendix N in part 52 to apply only to proceedings for combined licenses under subpart C of part 52 (appendix N in part 50 will continue to address proceedings for construction permits and operating licenses under that part).

To reflect the expanded scope of appendix N of part 52 and to ensure that all of the NRC's regulations use consistent terminology, the Commission is revising subpart D of part 2 as part of this final rulemaking. Inasmuch as the changes to the provisions in subpart D constitute revisions to the Commission's rules of procedure and practice, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

16. § 2.400, *Scope of subpart.*

This section is revised to refer to both appendix N of both part 50 and part 52, in order to reflect the Commission's determination that the appendix should be retained in both parts,

and that the procedures in the appendices (both of which refer to this subpart) should apply to applications for construction permits, operating reactors, and combined licenses of identical design. In addition, § 2.400 is revised to use the term “identical design,” instead of the former “essentially the same design,” so that subpart D and appendix N of part 50 and part 52 use identical terminology.

17. § 2.401, *Notice of hearing on construction permit or combined license applications pursuant to appendix N of 10 CFR parts 50 or 52.*

Paragraph (a) of § 2.401 is revised to indicate that notices of hearing will be published for both construction permits under part 50 and combined licenses under part 52. Notices of the issuance of operating licenses is addressed, as was the case under the former provisions of subpart D, in § 2.403. No other substantive changes are intended by this revision. Paragraph (b) remains unchanged.

18. § 2.402, *Separate hearings on separate issues; consolidation of proceedings.*

Both paragraphs of this section are revised to refer to applications under part 50 and part 52. No other substantive changes are intended by this revision.

19. § 2.403, *Notice of proposed action on applications for operating licenses pursuant to appendix N of 10 CFR part 50.*

This section is revised to refer to operating licenses issued under part 50, rather than part 52. This reflects the Commission's determination that appendix N of part 50 applies to construction permits and operating licenses, whereas appendix N of part 52 applies to combined licenses under subpart C of part 52.

20. § 2.404, *Hearings on applications for operating licenses pursuant to appendix N of 10 CFR part 50.*

This section is revised to make clarifying changes by adding references to a presiding officer, correctly referring to the Chief Administrative Judge, and removing a reference to the atomic safety and licensing board. No substantive changes are intended by this revision.

21. § 2.405, *Initial decisions in consolidated hearings.*

This section is revised by requiring the presiding officer to issue a separate partial initial decision on the common design. Section 2.405 is also revised by clarifying that the presiding officer may, if otherwise determined under the consolidation provisions of § 2.317(b), issue a consolidated decision for those proceedings. No other substantive changes are intended by this revision.

22. § 2.406, *Finality of decisions on separate issues.*

This section is revised to refer to both appendix N of both part 50 and part 52. No other substantive changes are intended by this revision.

23. § 2.407, *Applicability of other sections.*

This section is revised to correctly reference subparts C, L, and N of part 2. No other substantive changes are intended by this revision.

24. Section 2.500, *Scope of subpart.*

This section is revised by adding a conforming reference to subpart F of part 52 on manufacturing licenses.

25. Section 2.501, *Notice of hearing on application under subpart F of part 52 for a license to manufacture nuclear power reactors.*

This section is revised by adding a conforming reference to subpart F of part 52 on manufacturing licenses. In addition, paragraph (b) of this section is revised by removing the detailed requirements governing the content of the notice of hearing published in the *Federal Register*, and instead referencing proposed § 2.104(f). As previously discussed, the Commission is consolidating in § 2.104 the requirements governing the content of a notice of hearing with respect to part 52 licensing and regulatory approval processes (with the exception of standard design certifications, which are addressed in subpart H of part 2).

26. Sections 2.502, 2.503, and 2.504.

The text of these section are removed, and their places are reserved in the final rule, because the matters addressed in these sections, regarding finality and the referencing of a manufactured reactor in a combined license, are addressed with greater specificity in the revisions to subpart F of part 52.

27. Subpart F, *Additional Procedures Applicable to Early Partial Decisions on Site Suitability Issues in Connection with an Application for a Construction Permit or Combined License for Certain Utilization Facilities*

Subpart F provides special procedures for the acceptance, docketing, administrative consideration, the conduct of hearings, and the presiding officer's issuance of a partial initial decision in licensing proceedings where there is early submittal of site suitability information in connection with an application for a construction permit or operating license, as described in § 2.101(a-1). As discussed earlier, the Commission has revised § 2.101(a-1) to allow applicants for combined licenses under part 52

The Commission has reorganized subpart F in an attempt to improve its usability (the reorganization is reflected in the provisions of § 2.600, *Scope of subpart*). Requirements applicable to partial decisions in construction permit proceedings continue to be addressed in §§ 2.602 through 2.606; a new subheading is added before § 2.602 to reflect the subject matter of these sections. The new requirements applicable to partial decisions in combined license proceedings are in §§ 2.621 through 2.629; a new subheading is also added before § 2.621 to reflect the subject matter covered by these sections. Section 2.629, which has no analogous provisions in §§ 2.602 through 2.606, is added by the Commission to ensure that the finality of a presiding officer's partial initial decision in a combined license proceeding is clearly addressed

using regulatory language similar to that used in the finality provisions in part 52, e.g., §§ 52.39, 52.63, 52.98.

Section 2.601 is revised to correctly list subparts A, C, G, L, and N of part 2 as subparts which are either applicable to or may be utilized in proceedings under subpart F.

28. Section 2.800, *Scope and applicability.*

Subpart B of part 52 sets out the requirements applicable to Commission issuance of regulations granting standard design certification for nuclear power facilities. Standard design certifications are approved through a rulemaking proceeding, and, in concept, the applicant for a design certification may be considered as a petitioner for rulemaking. However, subpart H of part 2, which sets forth the Commission's procedures governing rulemaking, including petitions for rulemaking, did not specifically address design certification. Furthermore, based upon the Commission's experience with three final design certification rules and a proposed design certification rule, it is clear that some of the procedural requirements applicable to petitions for rulemaking are not well-suited to the administrative process for determining a design certification application, e.g., the existing prohibition against pre-application consultation with the NRC. These consultations between potential license applicants and the NRC staff are not currently prohibited and indeed are encouraged by the Commission to enhance NRC resource planning and to facilitate early identification and resolution of technical and regulatory issues. An application for design certification is more like a license application than a traditional petition for rulemaking, and the current prohibition against pre-application consulting appears to be inconsistent with the Commission's strategic objectives of safety, effectiveness, and management excellence. The Commission also believes, based upon its experience, that administrative provisions ordinarily applied in the context of licensing (e.g., docketing and

acceptance review, denial of application for failure to supply information), should also be available for application as appropriate in its determination of design certification applications.

For these reasons, the Commission is revising subpart H of part 2 to address standard design certifications. Section 2.800 is revised to delineate which provisions of subpart H are applicable to all petitions for rulemaking, and which provisions are applicable only to initial applications for design certification and applications for amendments to existing design certification rules filed by the original applicant (or successors in interest). The title of § 2.800 is revised to reflect the additional function of this section. New §§ 2.811 through 2.819 are added to address initial applications for design certification as well as applications for amendments to existing design certifications filed by the original applicant (or successors in interest), and are based upon §§ 2.101, 2.107, and 2.109. Petitions for amendment of existing design certification, which are filed by third parties other than the original applicant for that design certification (or successor in interest), will be treated as an amending petition for rulemaking under the provisions of §§ 2.801 through 2.810.

29. Section 2.801, *Initiation of rulemaking.*

In a conforming change, § 2.801 is revised to refer to applications for standard design certification rulemaking.

30. Section 2.811, *Filing of standard design certification application; required copies.*

New § 2.811 clarifies the requirements that are related to the filing of applications for standard design certifications. The requirements in this section are derived from procedural requirements for license applications located in several different regulations in part 50. Section 2.811(a), which is analogous to § 50.4(a), identifies the NRC addresses where an application for a standard design certification must be filed, and provides the requirements for electronic submission of a design certification application. Section 2.811(b), which is analogous to § 50.30(a)(1) and (3), provides that a standard design certification application must meet the written communications requirements in § 2.813. Section 2.811(c), which is analogous to § 50.30(a)(2), requires the applicant to have the capability to make and supply additional copies of the application upon NRC request. Section 2.811(d), which is analogous to the requirement in § 50.30(a)(4), requires the applicant to make a copy of the updated application for use by any party in a hearing conducted under subpart O of part 2 (a legislative-style hearing). Section 2.811(e), which addresses pre-application consultation with the NRC staff, provides that the potential applicant for a design certification may consult with the NRC on the subject matters listed in § 2.802(a)(1)(i) through (iii), including the procedure and process for filing and processing an application for a design certification. However, § 2.811(e) also allows the prospective standard design certification applicant to consult with the NRC staff on substantive technical and regulatory matters relevant to the design certification; the prohibitions in § 2.802(a)(2) do not apply to these consultations.

31. Section 2.813, *Written communications.*

New § 2.813 contains procedural and “housekeeping” requirements governing written communications with the NRC, and are derived from analogous requirements located in several different regulations in part 50. Section 2.813(a) is analogous to § 50.4(a). Section 2.813(b) is

analogous to § 50.4(c), and sets forth the requirement that written copies be submitted in permanent form on unglazed paper. Section 2.813(c) is analogous to § 50.4(d), and expresses the Commission's preference that the upper right corner of the first page of the applicant's submission set forth the specific regulation or other basis which instigated the written communication.

32. Section 2.815, *Docketing and acceptance review.*

New § 2.815 is analogous to § 2.101(a)(2), and permits the NRC to conduct a review to determine whether the application is complete (*i.e.*, addresses all matters specifically required by NRC regulation to be addressed in an application) and acceptable for docketing. Section 2.815(a) provides that the NRC may determine, in its discretion, the acceptability for docketing of an application based on the technical adequacy of the application, not just on the completeness of the application.

33. Section 2.817, *Withdrawal of application.*

New § 2.817 is analogous to § 2.107, and addresses the procedures that the NRC will follow if a design certification applicant withdraws its application. Section 2.817 also provides for a notice of action on the withdrawal on the NRC Web site if the notice of application was published on the NRC Web site.

34. Section 2.819, *Denial of application for failure to supply information.*

New § 2.819 is analogous to § 2.108, and states in paragraph (a) that the NRC may deny an application for a standard design certification if the applicant fails to respond to an NRC request for additional information concerning its application within 30 days of the request. Section 2.819(b) provides that the NRC will publish in the *Federal Register* a document denying the application. Section 2.819(b) also states that the NRC will publish a notice on the NRC's Web site denying the application if the NRC previously published a notice of receipt of the application on the NRC Web site.

G. Changes to 10 CFR Part 10.

1. Section 10.1, *Purpose*; and § 10.2, *Scope*.

Part 10, which contains the NRC's requirements and procedures for determining eligibility for granting access to Restricted Data and National Security Information, did not reflect the licensing and approval processes in part 52. Accordingly, the Commission made two changes to ensure that there are defined criteria and procedures governing requests for access to Restricted Data and National Security Information by individuals with respect to a license or approval under part 52.

Section 10.1 is revised by adding a new paragraph (a)(3), which refers to the eligibility of individuals for employment with NRC licensees and applicants, and holders of standard design approvals under part 52. Section 10.2(b) is revised so that it refers to standard design approvals under part 52 and applicants for consultants. This change will address the provision of services associated with design approvals, who may not, *per se*, be "employees."

H. Changes to 10 CFR Part 19.

Part 19, entitled *Notices, Instructions and Reports to Workers: Inspection and Investigations*, establishes the NRC's requirements for notices, instructions and reports to persons participating in NRC licensed and other regulated activities. For example, it requires licensees and applicants for licenses to post a copy of, *inter alia*, the regulations in 10 CFR parts 19 and 20, and NRC Form 3. NRC Form 3 provides a statement of rights and responsibilities to employees with respect to NRC requirements. Part 19 also establishes the rights and responsibilities of the NRC and individuals during interviews compelled by subpoena as part of a NRC inspection or investigation under Section 161.c of the AEA. Finally, part 19 prohibits, on the grounds of sex, the exclusion from participation in, or being subjected to discrimination under any program or activity licensed by the NRC. The regulatory authority for part 19 stems from Sections 211 and 401 of the Energy Reorganization Act of 1974, as amended (1974 ERA).

The NRC has identified a number of weaknesses with the former regulatory language in part 19. Formerly, part 19's regulatory requirements and proscriptions applied only to licensees who receive, possess, use or transfer material licensed under the NRC's regulations, including persons licensed to operate a production or utilization facility under 10 CFR part 50, but did not cover holders of 10 CFR part 52 licenses such as combined licenses, early site permits, and manufacturing licenses. Moreover, part 19 applied only to licensees who receive, possess, use or transfer materials licensed under 10 CFR parts 30 through 36, 39, 40, 60, 61, 63, 70 or 72 (including persons licensed to operate a production or utilization facility under part 50). Thus, the former regulations did not appear to address discrimination against an employee during "non-operational" activities such as manufacturing or construction of a nuclear power plant. Because the NRC's regulatory scheme relies upon the proper design, manufacture, siting,

and/or construction of a production or utilization facility; discrimination against an employee at any of these stages could have significant adverse public health and safety or common defense and security implications and effects. One would therefore expect that part 19 would apply to such non-operational activities. Finally, part 19 applied only to a “licensee” and activities authorized by a “license” (see, e.g., §§ 19.1, 19.2, 19.11, 19.20, 19.32), and did not extend to part 52’s non-licensing regulatory approvals, *i.e.*, standard design approvals and standard design certifications. Inasmuch as these non-licensing activities regulated under part 52 are not different in kind from the licensing which are currently subject to part 19 requirements, the NRC concludes that they should also be subject to the requirements in part 19.

Accordingly, the NRC is amending various provisions in part 19 to ensure that its provisions extend to applicants for and holders of part 50 construction permits, and combined licenses, early site permits and manufacturing licenses under part 52. In addition, the NRC extends part 19 to cover applicants for and holders of standard design approvals and standard design certifications. The NRC believes that its regulatory authority under Section 211 and Section 401 of the 1974 ERA is much broader than the former scope of part 19. The anti-discrimination proscriptions in Section 211 of the ERA apply to any “employer,” which the NRC regards as including non-licensee entities otherwise regulated by the NRC, such as applicants for and holders of standard design approvals, and applicants for standard design certifications. The Commission believes that the use of the term, “includes,” in paragraph (a)(2) of Section 211 of the 1974 ERA was not intended to be an exclusive list of the persons and entities subject to the anti-discrimination provisions in that section. The House Report on H.R. 776, which was adopted by Congress as the Energy Policy Act of 1992, states:

[Title V] also broadens the coverage of existing whistle blower protection provisions to include...*any other employer engaged in any activity* under the Energy Reorganization Act of the Atomic

Energy Act of 1954. (H.Rep. No. 102-474, part 8, 102d Congress, 2d Sess., at 78-79 (1992) (*emphasis added*))

There was no discussion of the statutory language in the conference report. (H.R. Conf. Rep. No. 102-1018, 102d Cong., 2d Sess. (1992)). The provisions in Section 401 of the ERA, prohibiting sex discrimination apply to “any program or activity carried on...under any title of this Act.” Accordingly, the NRC concludes that it has the authority to extend the former scope of part 19 to address the non-licensing regulatory approvals in part 52.

To implement the NRC’s broadening of the scope of part 19, §§ 19.1 and 19.2 are revised to explicitly refer to: (1) applicants for and holders of licenses and permits under part 52; (2) applicants for and holders of final design approvals; and (3) applicants for standard design certifications. The NRC notes that the existing provision in § 19.2 excluding part 19 from applying to NRC employees and NRC contractors remains unchanged in the final rule. To provide a convenient term for referring to persons and entities applying for, or granting non-licensed regulatory approvals in part 52, as well as any future regulatory processes, the NRC is amending § 19.3 to the terms, *regulated activities*, and *regulated entities*. Regulated entities are defined to include (but not be limited to) applicants for and holders of standard design approvals under subpart E of part 52, and applicants for standard design certifications under subpart B of part 52.

Section 19.11 establishes requirements for posting of notices to workers. Because §§ 19.11(a)(2) and (a)(4) contain posting requirements which are not relevant to early site permits, manufacturing licenses, standard design approvals, and standard design certifications, the NRC delineated in § 19.11(b) the applicable posting requirements for those regulatory processes. Section 19.11(c) is reserved for future Commission use.

Sections 19.14 and 19.20 are revised to apply to regulated entities, as well as licensees.

Section 19.31, governing exemptions from part 19, is revised to use language consistent with § 50.12 and § 52.7. Unlike the former regulation, which limits a request for exemption to a “licensee,” the final rule allows “interested persons,” as well as licensees to request an exemption from one or more provisions of part 19. This will allow applicants for and holders of non-license regulatory vehicles in part 52 (standard design approvals and design certifications) to request exemptions from part 19. The broadened scope of persons that will be allowed to request an exemption is consistent with most of the exemption provisions throughout the NRC’s regulations in Title 10 of the CFR, including the specific exemption provision in part 50 (*i.e.*, § 50.12).

Section 19.32 is revised to more closely track the broad scope of statutory language in Section 401 of the 1974 ERA, which is not limited to licensing, but extends the sex discrimination prohibition to “any...activity carried on...under any title” of the ERA. By using the statutory language in the proposed rule, the NRC believes that the regulations cover not only the existing non-license regulatory vehicles in part 52, but any other regulatory approaches that the NRC may adopt in the future (Section 401 of the 1974 ERA applies to NRC regulatory activities under the AEA, inasmuch as the 1974 ERA transferred the AEA regulatory authority from the old AEC to the NRC, see 1974 ERA, Sec. 104(c)).

I. Changes to 10 CFR Part 20.

1. Section 20.1002, Scope.

10 CFR part 20 applies to persons licensed by the NRC to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production

or utilization facility. Accordingly, § 20.1002 is revised by adding a conforming reference to part 52, which sets forth a process for licensing a utilization facility.

2. Section 20.1401, *General provisions and scope.*

This section on decommissioning of facilities is revised to add a conforming reference to facilities licensed under 10 CFR part 52.

3. Section 20.1406, *Minimization of contamination.*

Section 20.1406 requires applicants for licenses, other than renewals, after August 20, 1997, to describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. The NRC is adding conforming changes to § 20.1406 in the final rule. These conforming changes to address part 52 were inadvertently overlooked in the proposed rule. Section 20.1406 contains requirements that relate both to design and operation of a facility and therefore applies in whole or in part to design approvals, design certifications, manufacturing licenses, and combined licenses. The final rule divides § 20.1406 into two paragraphs. Paragraph (a) addresses applicants for licenses, other than early site permits and manufacturing licenses and contains all of the requirements in former § 20.1406. Paragraph (b) addresses applicants for standard design certifications, standard design approvals, and manufacturing licenses and only contains the requirements related to design. If a combined license applicant references a design approval, design certification, or a reactor manufactured under a manufacturing license that has addressed the design portion of this

requirement under paragraph (b), then it would only need to address the remaining “operational” requirements under paragraph (a).

4. Section 20.2203, *Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.*

Sections 20.2203(c) and (d) are revised to add a reference to holders of combined licenses to the procedures on submitting reports.

J. Changes to 10 CFR Part 21.

Part 21 implements the reporting requirements in Section 206 of the ERA. The proposed part 52 rule published in 2003 set forth the NRC’s proposals as to how Section 206 reporting and, therefore, part 21 applicability should be extended to early site permits, standard design certifications, and combined licenses. However, the 2003 proposed rule did not address Section 206 reporting requirements with respect to standard design approvals or manufacturing licenses. Moreover, the proposals were developed without the benefit of the NRC’s in-depth consideration of the issues as applied in the context of the early site permit applications that are currently before the NRC. Accordingly, NRC withdrew its earlier proposal and developed a more complete and integrated rule on Section 206 reporting under part 21 and § 50.55(e). As discussed previously, § 50.55(e) sets forth the Section 206 reporting requirements applicable to holders of construction permits, combined licenses, and manufacturing licenses.

Key principles of reporting under Section 206 of the ERA.

The NRC believes that the extension of NRC’s reporting requirements implementing Section 206 of the ERA to part 52 licensing and approval processes should be consistent with three key principles. First, NRC regulatory requirements implementing Section 206 of the ERA should be a legal obligation throughout the entire “regulatory life” of an NRC license, a standard design approval, or standard design certification. Second, reporting of defects or failures to comply associated with substantial safety hazards should occur whenever the information on potential defects would be most effective in ensuring the integrity and adequacy of the NRC’s regulatory activities under part 52 and the activities of entities⁷ subject to the part 52 regulatory regime. Third, each entity conducting activities within the scope of part 52 should develop and implement procedures and practices to ensure that it fulfills its Section 206 of the ERA reporting obligation in an accurate and timely manner.

First principle - Section 206 of the ERA applies throughout “regulatory life.”

The first principle, that NRC regulatory requirements implementing Section 206 must extend throughout the entire “regulatory life” of a part 52 process, reflects the regulatory pattern inherent in part 52, whereby certain designated licenses or approvals—e.g., an early site permit, nuclear power reactor manufactured under a manufacturing license, or a design certification—are capable of being referenced in a subsequent nuclear power plant licensing application. Under the part 52 regulatory scheme, a referenced NRC approval constitutes the NRC’s basis for the licensing action within the scope of the prior Commission approval, and becomes part of the “licensing basis” for that plant. However, if Section 206 of the ERA reflects that effective NRC decision-making and regulatory oversight require accurate and timely

⁷Throughout this discussion, reference to entities, licensees and/or applicants includes the contractors and subcontractors of those entities, licensees and/or applicants.

information about defects and failures to comply associated with substantial safety hazards, then Section 206 of the ERA should apply whenever necessary to support effective NRC decision-making and regulatory oversight of the referencing licenses and regulatory approvals. To put it in different terms, if the NRC decision that it may safely issue a license depends in part upon an earlier NRC safety determination for a referenced license, standard design approval, or standard design certification, it follows that a safety issue with respect to the referenced license, design approval, or design certification has safety implications for the referencing license or design certification, and the continuing validity of the NRC's licensing decision. Thus, the NRC concludes that the need for Section 206 reporting should not be limited to those licenses and approvals under part 52 which are referenced or "relied upon" in a subsequent nuclear power plant licensing application (*viz.*, early site permits, standard design approvals, standard design certifications, and manufacturing licenses), but rather should extend to licenses and approvals that are capable of being referenced in a future licensing application. In other words, they must extend until there can be no further potential safety implications for a referencing license or approval.

The NRC believes that the beginning of the "regulatory life" of a referenced license, standard design approval, or standard design certification under part 52 occurs when an application for a license, design approval, or design certification is docketed. Docketing of an application marks the start of the NRC's formal safety and environmental review of the application, and therefore the initiation of the NRC's need for accurate and timely information to support its regulatory review and approval. However, the NRC cautions that this does not mean that an applicant is without Section 206 responsibilities for pre-application activities. As the NRC staff discussed in a June 22, 2004, letter to the Nuclear Energy Institute (NEI) (ML040430041) in the context of an early site permit, there are two aspects, namely, a "backward looking" or retrospective aspect with respect to existing information, and a "forward

looking” or prospective aspect with respect to future information. The retrospective obligation is that the early site permit holder and its contractors, must report all known defects or failures to comply in “basic components,” as defined in part 21. The prospective obligation is that the early site permit holder and its contractors must report all defects or failures to comply in basic components discovered subsequent to early site permit issuance. The early site permit holder and its contractors are required to meet these requirements, and must continue to meet them throughout the term of the early site permit. Accordingly, safety-related design and analysis or consulting services should be procured and controlled, or dedicated, in a manner sufficient to allow the early site permit holder and its contractors, as applicable, to comply with the above described reporting requirements of Section 206, as implemented by 10 CFR 50.55(e) and part 21.

The NRC believes that the end of regulatory life occurs at the later of: (1) the termination or expiration of the referenced license, standard design approval, or standard design certification; or (2) the termination or expiration of the last of the license or design certification *directly or indirectly referencing* the (referenced) license, design approval, or design certification. For example, if the NRC approves a standard design approval, which is subsequently referenced in a final standard design certification rule, and that standard design certification is, in turn referenced in a combined license issued by the NRC, the “end” of the regulatory life occurs when the authorization to operate under the combined license is terminated (ordinarily, under the provisions of § 52.110). As long as a referenced combined license continues to be effective, the “regulatory life” of a referenced license, standard design approval, standard design certification, or manufactured reactor (as applicable) must also continue and cannot be deemed to have ended.

Some commenters argued that the NRC’s regulatory interests would be met if reporting under Section 206 of the ERA were limited to the referencing applicant/licensee, and that there

should be no ongoing part 21 reporting obligation imposed on the early site permit holder, original applicant for a standard design certification, or holder of a part 52 regulatory approval. Under this proposal the referencing applicant and licensee would satisfy its obligation by an appropriate contractual provision between the referencing applicant/licensee and the entity “supplying” the referenced license or regulatory approval. Although this could be a viable alternative for some combined licenses, early site permits, and standard design approvals, the approach would not be effective in the following contexts. This approach would not result in reporting of defects to the NRC by the applicant of the early site permit or standard design certification, which violates the NRC’s second principle (discussed more fully in the next section). In addition, this approach would not result in reporting where there is no contractual relationship between the combined license applicant/licensee and the original applicant of the standard design certification. Because the approach suggested by these commenters does not satisfy the NRC’s regulatory objectives, it is not adopted.

One of the original applicants for the current standard design certifications stated that any arguable Section 206 requirements must logically end upon expiration of the standard design certification, inasmuch as expiration marks the end time that the standard design certification may be referenced. The NRC disagrees with this position. Under § 52.55(b) of the current regulations, a standard design certification continues to be effective in a hearing for a combined license or operating license docketed before the expiration date, and in a hearing under § 52.103 for authority to load fuel and operate. At minimum, the original standard design certification applicant should be subject to Section 206 requirements until the proceeding is completed. Beyond the minimum requirements, the NRC also believes that the original design certification applicant’s Section 206 obligations should continue until operation is no longer authorized in accordance with § 50.82(a)(2) for the last operating license or combined license referencing that standard design certification. The NRC believes that the regulatory need for

information concerning defects in a standard design certification continues throughout the operating life of a license referencing that design certification; the relevance of and the NRC's need for this information, if subsequently discovered by the original design certification applicant, does not diminish simply because the standard design certification may no longer be referenced.

Second principle - Notification occurs when information is needed.

The second principle is focused on ensuring that the NRC, its licensees, and license applicants receive information on defects at the time when the information would be most useful to the NRC in carrying out its regulatory responsibilities under the AEA, and to the licensee or applicant when engaging in activities regulated by the NRC. A result of this principle is that reporting may be delayed if there is no immediate consequence or regulatory interest in prompt reporting, and that delayed reporting will actually occur when necessary to support effective, efficient, and timely action by the NRC, its licensees and applicants. Applying the second principle and its result to part 52 processes, the NRC believes that immediate reporting is required throughout the period of pendency of an application, be it a license, a standard design approval, or a standard design certification. Allowing an applicant to delay the reporting of a defect would appear to be inconsistent with the NRC's statutory mandate to provide adequate protection to public health and safety and common defense and security. Even if delayed reporting would allow the NRC an opportunity to modify its prior safety finding with respect to the license, design approval, or design certification, the delayed consideration is inconsistent with one of the fundamental purposes of part 52, viz., to provide for early consideration and resolution of issues in a manner that avoids the potential for delay during licensing of a facility. Accordingly, the Commission has determined that the NRC's requirements implementing

Section 206 of the ERA must extend to applicants (and their contractors and subcontractors) for all part 52 processes (licenses, early site permits, design approvals, and design certifications). Some commenters stated that part 21 should not apply to applicants and claimed that the NRC's proposal was contrary to the ERA. For the reasons stated previously, the Commission does not agree with that position. However, once an application has been granted, the Commission has decided that immediate reporting of subsequently-discovered defects is not necessary in certain circumstances. For those part 52 processes which do not authorize continuing activities required to be licensed under the AEA, but are intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals, the reporting of defects or failures to comply associated with substantial safety hazards may be delayed until the time that the part 52 process is first referenced. The Commission's view is based upon its determination that a defect with respect to part 52 processes should not be regarded as a "substantial safety hazard," because the possibility of a substantial safety hazard becomes a tangible possibility necessitating NRC regulatory interest only when those part 52 processes are referenced in an application for a license, early site permit, design approval, or design certification.

Some commenters believe that these reporting requirements should not apply to a holder of an early site permit or a vendor of a standard design until the ESP or standard design is referenced in a COL application. As stated previously, the Commission agrees that reporting may be delayed until the approval, certification, or permit is referenced. After referencing, the holder (or in the case of a design certification, the applicant who submitted the application leading to the final design certification regulation) must make the necessary notifications to the NRC as well as provide final engineering. The notification must address the period from the Commission adoption of the final design certification regulation up to the filing of the application referencing the final design certification regulations. Thereafter, notice must be made in the

ordinary manner. The notification obligation ends when the last license referencing the design certification is terminated.

Third principle - Procedures and practices must be implemented to ensure accurate and timely reporting.

The third principle (*viz.*, each entity conducting activities under the purview of part 52, should develop and implement procedures and practices to ensure that the entity accurately and timely fulfils its reporting obligation as delineated in the NRC's regulations), is intended to ensure the effectiveness of each entity's reporting processes. This is especially true where there is a potential for substantial passage of time between the discovery of a defect and the reporting of the defect, as may be allowed by the NRC consistent with the second principle. For example, following issuance of a final standard design certification regulation, if the original applicant determines that there is a substantial safety hazard, that applicant need not report the discovery until the time that the design certification rule is referenced—which may be as long as 15 years from the date of the final rule. Given the substantial time that may pass between the time of discovery and the date of reporting, it is imperative that the original standard design certification applicant develop and implement procedures from the time of effectiveness of the final design certification regulations.

The result of the third principle, consistent with part 21's current requirements, is that licensees, license applicants, and other entities seeking a design approval or design certification, must have contractual provisions with their contractors, subcontractors, consultants, and other suppliers which notify them that they are subject to the NRC's regulatory requirements on reporting and the development and implementation of reporting procedures. This result is set forth in §§ 21.31 and 50.55(e)(7).

Division of implementing requirements between Part 21 and § 50.55(e).

Under the Commission’s current regulatory structure, persons and entities engaged in construction (or the functional equivalent of construction) are subject to reporting requirements under § 50.55(e). Persons and entities engaged in all other activities within the purview of Section 206 of the ERA are subject to the requirements in part 21 and/or § 50.55(e). The revised part 21 and § 50.55(e) reflect the Commission’s determination to retain this divided regulatory structure. The NRC believes that the only part 52 processes that authorize “construction” or its functional equivalent are manufacturing licenses and combined licenses before the Commission makes the finding under § 52.103(g). Therefore, the reporting requirements with respect to Section 206 of the ERA for manufacturing licenses and combined licenses before the Commission makes the finding under § 52.103(g) are contained in § 50.55(e). The requirements in part 21 apply after the Commission makes the finding under § 52.103(g) for a combined license. Part 21 was revised to explicitly apply to the remaining part 52 processes, *i.e.*, early site permits, standard design approvals, and standard design certifications. Table A-1 provides a summary of the applicability of part 21 and § 50.55(e) to each of the various approvals under part 52.

Table A-1

Applicability of NRC Requirements Implementing Section 206 of the Energy Reorganization Act to Part 52 Licensing and Approval Processes

Part 52 Licensing or Approval Processes	Applicable NRC Requirement Implementing Section 206 of the ERA	Sanctions	
		Civil	Criminal
Early Site Permit (ESP)			

Application	part 21	21.61	21.62
Issuance of ESP	part 21	21.61	21.62
Standard Design Approval (SDA)			
Application	part 21	21.61	21.62
Issuance of SDA	part 21	21.61	21.62
Standard Design Certification Rule (DCR)			
Application	part 21	21.61	21.62
Final DCR Rulemaking	part 21	21.61	21.62
Combined License (COL)			
Application	50.55(e)	50.110	50.111
COL before § 52.103 Authorization	50.55(e)	50.110	50.111
COL after § 52.103 Authorization	part 21	21.61	21.62
Manufacturing License (ML)			
Application	50.55(e)	50.110	50.111
Issuance of ML	50.55(e)	50.110	50.111

Reporting requirements for early site permits.

If the ESP holder becomes aware of a significant safety concern with respect to its site (e.g., that the specified site characteristics for seismic acceleration is less than the projected acceleration due to new information), the concern should be reported to the NRC so that it may be considered in the review of any future application referencing the ESP. As stated previously, the reporting may be delayed until the ESP is referenced. This reporting attains special importance given the NRC's proposal not to impose an updating requirement for ESP information other than that related to emergency preparedness. In order for the applicant for an ESP to have the capability to report to the NRC any known significant safety concerns with

respect to its site, or any safety concerns of which it may subsequently become aware (*i.e.*, to be able to report any defects or failures to comply associated with substantial safety hazards under part 21) the ESP applicant would have to have a program in place for implementing the requirements of 10 CFR part 21. The applicant's program may be inspected by the NRC as part of the application review. Approval of the ESP application would be subject to approval of the part 21 program.

Some commenters claimed that there is no practicable method for ESP applicants or holders to determine whether an error in siting information creates a substantial safety hazard and, therefore, part 21 should not be applicable to ESP applicants or holders. The Commission does not agree with this position. As stated previously, the ESP holder and its contractors can determine defects or failures to comply with "basic components," as defined in part 21. This information is necessary in order to support effective NRC decision-making and regulatory oversight of the referencing licenses and approvals.

Applicability of part 21 to contractors or subcontractors of an ESP applicant or holder.

In accordance with 10 CFR 21.31, the purchaser of a basic component must state in the procurement documents for the basic component that part 21 is applicable to that procurement. As explained previously, services that are required to support an early site permit application (*e.g.*, geologic or seismic analyses, etc.) that are safety-related and could be relied upon in the siting, design, and construction of a nuclear power plant, are to be treated as basic components as defined in part 21. Therefore, these services must be either purchased as basic components, requiring the service provider to have an appendix B to part 50 QA program, as well as its own part 21 program, or the early site permit applicant could dedicate the service in

accordance with part 21, which requires the dedication process itself to be controlled under an appendix B to part 50 QA program.

Reporting requirements for standard design approvals.

A standard design approval represents the NRC staff's determination regarding the acceptability of the design for a nuclear power reactor (or major portions thereof). Although a standard design approval does not represent the NRC's final determination as to the acceptability of the design, it nonetheless represents a substantial expenditure of agency resources in reviewing the design. A standard design approval may be referenced in a subsequent application for a design certification, construction permit, operating license, combined license, or manufacturing license. Accordingly, consistent with the first principle, the final rule imposes requirements implementing Section 206 of the ERA on applicants for and holders of standard design approvals.

A standard design approval does not authorize construction of a nuclear power plant; it merely constitutes the NRC staff's approval of the design of a nuclear power reactor (or major portion thereof). Therefore, the requirements implementing Section 206 of the ERA, which are applicable to standard design approvals, were placed in part 21, as opposed to § 50.55(e).

Reporting requirements for standard design certification regulations.

A standard design certification represents the NRC's approval by rulemaking of an acceptable nuclear power reactor design, which may then be referenced in a subsequent combined license or manufacturing license application. Consistent with the first principle, the Commission imposed Section 206 of the ERA reporting requirements on applicants for design

certifications, including applicants whose designs are certified in a final design certification rulemaking. As with a standard design approval, a design certification does not actually authorize construction. Accordingly, the NRC revised §§ 21.2, 21.3, 21.21, 21.51, and 21.61 to explicitly refer to an applicant for a standard design certification, rather than § 50.55(e).

Some commenters have asserted that because there is no “holder” or licensee, the NRC is without authority under Section 206 of the ERA to impose part 21 and/or § 50.55(e) evaluation and reporting requirements on applicants for standard design certification. The NRC disagrees with this assertion. The statute by its terms does not limit its reach to licensees; rather, the statute applies to any individual or responsible officer of a firm “constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated....” The NRC believes that an applicant for a standard design certification, by submitting its application, is constructively “supplying” a “component” (the nuclear power plant) for use in a future “facility...licensed” by the NRC. One of the consequences of the design certification provisions in part 52 is the ability of the applicant to subsequently offer its design with additional, value-added services. Thus, applying for and facilitating NRC adoption of a final standard design certification regulation is simply a partial step in the overall activity of “supplying” the certified design to potential nuclear power plant license applicants.

Alternatively, one could treat the standard design certification applicant as supplying a component of an “activity” which is “otherwise regulated” by the NRC. Under this interpretation, the “activity...otherwise regulated by the NRC” can be viewed as the design certification rulemaking, and/or the entire part 52 regulatory regime whereby a design certification rule is referenced in a subsequent licensing application. The NRC concludes that under either interpretation, Section 206 of the ERA provides ample statutory authority for the NRC to impose regulations implementing Section 206 on design certification applicants, during the pendency of

the application before the NRC, as well as after NRC adoption of a final design certification regulation (for those applicants whose application is granted).

As with standard design approvals, a standard design certification does not authorize construction of a nuclear power plant; it constitutes the NRC's approval of the design of a nuclear power plant. Therefore, the requirements implementing Section 206 of the ERA which are applicable to design certifications were placed in part 21, as opposed to § 50.55(e).

Reporting requirements for combined licenses.

A combined license authorizes both construction of a nuclear power plant, and loading of fuel and operation if the NRC makes the findings specified in § 52.103. As such, the application of the first and second principles to combined licenses is the most straightforward of all the part 52 processes. Under the final rule, the NRC's requirements implementing Section 206 of the ERA would apply throughout the regulatory life of the combined license, *i.e.*, from docketing of the application until termination of the combined license.

To maintain the current division between § 50.55(e) and part 21 with respect to NRC requirements implementing Section 206 of the ERA, the NRC revised § 50.55(e) to make its provisions applicable to each holder of a combined license under part 52 before the effective date of the NRC's finding under § 52.103(g), and to revise part 21 to clarify that its provisions apply to each holder of a combined license on the effective date of the Commission's authorization under § 52.103(g).

Reporting requirements for manufacturing licenses.

Under subpart F of part 52, a manufacturing license would constitute both the NRC's approval of a final nuclear power reactor design, as well as approval to manufacture one or more reactors in accordance with approved programs and procedures. The manufactured reactors would then be transported offsite and incorporated into nuclear power facilities by holders of combined licenses—who may be different entities than the holder of a manufacturing license. Given the possibility that the manufacturing license holder is different from the combined license holder whose facility uses the manufactured reactor, the NRC believes that the combined license holder must be kept informed of any significant issue with design or manufacture of the reactor, to ensure that they evaluate the significance of these matters for their facility and undertake any necessary action to assure public health and safety and common defense and security. Furthermore, unlike a standard design certification, the financial resources necessary to obtain a manufacturing license will, as a practical matter, result in manufacturing beginning immediately after issuance of the manufacturing license. There will be no interim period similar to a design certification where there is no activity occurring under the manufacturing license. Accordingly, in compliance with the first and second principles, the NRC proposes that Section 206 of the ERA requirements should apply continuously from the filing of the application, until the manufacturing license expires or is otherwise terminated by the NRC.

A manufacturing license holder would essentially be conducting the same activities as a construction permit holder, albeit with several differences.⁸ Nonetheless, the NRC believes that manufacturing is similar to construction such that the NRC's requirements implementing

⁸These key differences are, first, the design of the manufactured plant would be approved before manufacturing commences, unlike the historical practice with construction permits. Second, a single manufacturing license may authorize the manufacture of multiple reactors, with the manufacturing process to be accomplished in a controlled setting rather than as a "field" operation. This is unlike the historical approach where non-standardized nuclear power facilities were constructed onsite using a "roving" workforce. Third, the manufacturing license will specify the inspections, tests, and acceptance criteria for determining successful manufacturing.

Section 206 of the ERA which are applicable to manufacturing licenses, are contained in § 50.55(e). Accordingly, the NRC revised § 50.55(e) to specifically apply its provisions to holders of manufacturing licenses.

K. Change to 10 CFR Part 25.

1. Section 25.35, *Classified visits*.

Part 25 sets forth the NRC's requirements governing the granting of access authorization to classified information to certain individuals. Section 52.35, which requires that licensees and certificate holders minimize the number of classified visits, did not, by its terms, apply to applicants for standard design certifications, and applicants for or holders of standard design approvals. Accordingly, § 25.35 is revised to refer to an applicant for a standard design certification under part 52 (including the applicant after the NRC adopts a final standard design certification rule), and the applicant for or holder of a standard design approval under part 52.

L. Changes to 10 CFR Part 26.

1. Section 26.2, *Scope*, § 26.10, *General performance objectives*; and Appendix A to Part 26.

Part 26, which sets forth the NRC's requirements governing fitness-for-duty, currently uses a two-part regulatory regime for the application of fitness-for-duty requirements. A holder of an operating license for a nuclear power plant is required to implement all of the provisions in

part 26. By contrast, a holder of a construction permit is required to implement a subset of part 26 requirements - §§ 26.10, 26.20, 26.23, 26.70, and 26.73.

The NRC has extended the applicability of parts 26 to 52, in keeping with the existing two-part regulatory regime, so that the full array of requirements in part 26 apply to a combined license holder after the date that the NRC authorizes makes the finding under § 52.103(g), analogous to holder of an operating license under part 50. By contrast, holders of combined licenses, before the date that the NRC makes the § 52.103(g) findings, are required to comply with the more limited set of part 26 provisions currently applicable to construction permit holders. Similarly, holders of manufacturing licenses under subpart F of part 52 are treated the same as holders of construction permits. Finally, persons authorized to conduct the limited construction activities allowed under § 50.10(e)(3) are also treated the same as a construction permit holder. The final rule accomplishes this by: (1) revising § 26.2(a) to refer to combined license holders after the date that the NRC makes the finding under § 52.103(g); (2) revising § 26.2(c) to refer to a holder of a combined license before the date that the NRC makes the finding under § 52.103(g), a holder of a manufacturing license under subpart F of part 52, and a person authorized to conduct the activities under § 50.10(e)(3); (3) revising § 26.10(a) to refer to the personnel of a holder of a manufacturing license and those authorized to conduct the activities under § 50.10(e)(3); and (4) revising appendix A to part 26, paragraph 1.1(1) to include a reference to a holder of combined license after the date that the NRC makes the finding under § 52.103(g).

The NRC believes that part 26 need not be extended to cover applicants for and holders of early site permits, standard design approvals, and applicants for standard design certifications under part 52. These activities present less of a concern with respect to public health and safety, and common defense and security, as compared with construction permits, manufacturing licenses, operating licenses and combined licenses. None of these regulatory

approvals or design certification regulations authorize the construction, manufacture, or operation of a facility, nor do they authorize possession of special nuclear material (SNM). The adverse impacts on public health and safety or common defense and security attributable to any fitness-for-duty issues are likely to be of a much lower level of significance, as compared to issues that may occur during construction, manufacture, operation, or possession of SNM. The NRC believes that the potential benefits of imposing the fitness-for-duty requirements are not justified in view of the regulatory burden to be imposed upon such applicants and holders. Accordingly, these requirements will not be imposed on applicants for and holders of standard design approvals, and applicants for standard design certifications under part 52.

M. Changes to 10 CFR Part 51.

The NRC is making several conforming changes to part 51 to clarify the environmental protection regulations applicable to the various part 52 licensing processes.

NEPA Compliance for Design Certifications.

For each of the four design certification rules in appendices A, B, C, and D of part 52, the NRC prepared an environmental assessment which: (1) provides the bases for a Commission finding of no significant environmental impact (FONSI) for issuance of the design certification regulation; and (2) identifies and addresses the need for incorporating SAMDAs into the design certification rule. Based upon this experience, the NRC is making changes to part 51 to accomplish two objectives.

First, the NRC is eliminating the need for the NRC to prepare essentially repetitive discussions in environmental assessments supporting a FONSI on issuance of a final standard

design certification regulation. Each of the environmental assessments and FONSI's prepared to date conclude that there is no significant environmental impact associated with NRC issuance of a final design certification regulation because a design certification does not authorize either the construction or operation of a nuclear power facility. Design certification represents the NRC's pre-approval of the design for the nuclear power facility, but does not authorize manufacture or construction. For the design certification to have practical effect, it must be referenced in an application for a combined license. Therefore, the environmental effects of construction and operation of a nuclear power facility using the referenced design certification are to be addressed in the EIS for the combined license. This is practical inasmuch as the full scope and details of the benefits and environmental impacts of constructing and operating a nuclear power reactor using the design approved in the design certification are most likely known at the time when the design certification is proposed to be used in a specific nuclear power facility at a particular site; this rationale will remain the same for all future design certifications. The NRC is revising part 51 to eliminate the need for the NRC to make repetitive findings of no significant environmental impact for future design certifications and amendments to design certifications.

Second, the NRC is requiring that SAMDAs be addressed at the design certification stage. SAMDAs are alternative *design* features for preventing and mitigating severe accidents, which may be considered for incorporation into the proposed design. The SAMDA analysis is that element of the severe accident mitigation alternatives analysis dealing with design and hardware issues. At the design certification stage, the NRC's review is directed at determining if there are any cost beneficial SAMDAs that should be incorporated into the design, and if it is likely that future design changes would be identified and determined to be cost-justified in the future based on cost/benefit considerations. It is most cost effective to incorporate SAMDAs into the design at the design certification stage. Retrofitting a SAMDA into a design certification

once site-specific design and engineering for a nuclear power facility has been completed would increase the cost of implementing a SAMDA. The retrofitting costs continue to increase in ensuing stages of facility construction and operation. For these reasons, the NRC believes that environmental assessments for design certifications should address SAMDAs. However, under the former provisions of part 51, both the environmental information submitted by the design certification applicant, and the environmental assessment prepared by the NRC, are directed either at determining whether an EIS must be prepared, or that a FONSI is justified. Accordingly, the NRC is requiring that SAMDAs be addressed in environmental reports and environmental assessments for design certifications.

The NRC is making a number of changes to accomplish these two objectives. The NRC is redesignating existing § 51.55 as § 51.58, and is adding new § 51.55 to indicate that an environmental report submitted by the design certification applicant must be directed towards addressing the costs and benefits of possible SAMDAs, and presenting the bases for not incorporating identified SAMDAs into the design to be certified. The environmental report for an applicant seeking to amend an existing design certification would be somewhat narrower by focusing on if the design change which is the subject of the amendment, renders a SAMDA previously rejected to become cost-beneficial, and if the design change results in the identification of new SAMDAs that may be reasonably incorporated into the design certification.

The NRC is revising § 51.30 to provide for a new § 51.30(d) establishing the scope of an environmental assessment for a design certification. The NRC is adding §§ 51.32 (b)(1) and (2) to set forth the NRC's generic determination of no significant environmental impact associated with issuance of a final or amended design certification rule. This is, essentially, the legal equivalent of a categorical exclusion. The NRC is including an explicit statement of no significant environmental impact in § 51.32. The NRC believes that external stakeholders will better understand the nature of the Commission's action by doing so. The NRC is modifying

§ 51.31 by adding § 51.31(b) specifying the information on the environmental assessment to be included in the proposed rulemaking on the design certification published in the *Federal Register*.

The NRC is revising § 51.50(c)(2) to indicate that if a combined license application references a design certification then the combined license applicant's environmental report may reference the SAMDA discussion in the design certification environmental assessment as part of its SAMDA analysis, but must contain information demonstrating that the site characteristics for the combined license site falls within the site parameters in the design certification environmental assessment.⁹

Finally, the NRC is adding § 51.75(f) to provide that if a combined license application references a design certification, then the combined license EIS will incorporate by reference the design certification environmental assessment, and summarize the SAMDA analysis and conclusions of the environmental assessment.

NEPA Compliance for Manufacturing Licenses.

The NRC believes that its current approach for meeting the Commission's NEPA responsibilities for standard design certifications should be extended to manufacturing licenses for nuclear power reactors. Under subpart F to part 52, a manufacturing license is similar to a standard design certification in that a final nuclear power reactor design would be approved. Therefore, the NRC is requiring that the environmental effects of construction and operation of a nuclear power facility using a manufactured reactor would be addressed in the EIS for the

⁹The design certification applicant may have chosen to specify site parameters for the design certification safety review under § 52.79 which differ from the site parameters specified in the environmental report for its design. If such a design certification is referenced in a combined license application, the combined license applicant must demonstrate that the two differing sets of site parameters are met, in order for the full panoply of issue finality provisions in § 52.63 to apply in the combined license proceeding.

combined license application for a nuclear power facility using a manufactured reactor, rather than in an environmental assessment or EIS at the manufacturing license stage.

Further, the NRC does not believe that NEPA requires the NRC to address the environmental impacts of actually manufacturing a nuclear power reactor licensed under subpart F of part 52, either at the manufacturing license stage or at the combined license stage where an application proposes to use a manufactured reactor. The manufacturing license approves the final design of the manufactured reactor, the organization and technical procedures for designing and manufacturing the reactor, and the ITAAC that are to be used by the licensee in determining whether the reactor has been properly manufactured in accordance with NRC requirements and the manufacturing license, and the possession (but not the use or transport offsite) of the manufactured reactor. The manufacturing license does not approve any specific location, building, or facility where the actual manufacture of the reactors may occur,¹⁰ and the NRC does not require the applicant for the manufacturing license to submit any information on these matters as part of its application. These matters are commercial matters generally unrelated to the NRC's regulatory jurisdiction. The Federal Aviation Administration (FAA) does not prepare an EIS when issuing a production certificate under 14 CFR part 21, subpart G, authorizing the production of an aircraft or component in conformance with a type certificate. See Federal Aviation Agency Order 1050.1E, Sec. 308c (June 8, 2004). Because the NRC does not approve any specific location or facility in which to manufacture any component of or the reactor licensed under the manufacturing license, it would be speculative for the NRC to describe and assess the environmental impacts of manufacturing. NEPA does not require that an EIS address speculative impacts. The NRC also notes that EISs prepared in

¹⁰A reactor manufactured outside of the United States would not be within the scope of a manufacturing license under subpart F of part 52, by virtue of proposed § 52.9, which states that no license shall be deemed to have been issued for activities which are not under or within the jurisdiction of the United States.

the past for construction permits and operating licenses under part 50, as well as current environmental assessments for nuclear power plant license amendments, have never considered the offsite environmental impacts of fabricating systems and components by vendors and subcontractors, even for circumstances where the fabrication activities are subject to NRC regulatory jurisdiction (e.g., under applicable provisions of parts 19 and 21). For these reasons, the NRC concludes that NEPA does not require the NRC to address, either at the manufacturing license stage or at the combined license stage where the application proposes to use a manufactured reactor, the speculative impacts of manufacturing a reactor offsite at a location or in a facility not specified or approved in the manufacturing license.

The NRC is making a number of changes to part 51, in some cases parallel to those described previously with respect to design certifications, consistent with its views on manufacturing licenses. The NRC is revising existing § 51.54 to clarify that an environmental report for a manufacturing license must address the costs and benefits of SAMDAs and the bases for not incorporating SAMDAs into the design of the reactor to be manufactured, and to state that the environmental report need not address the impacts of manufacturing a reactor under the manufacturing license. The NRC is removing both § 51.20(b)(6), which formerly required preparation of an EIS for issuance of a manufacturing license, and § 51.76, which formerly addressed the subject matter of an EIS for a manufacturing license, from part 51.

The NRC is revising § 51.30(f) to establish the scope of an environmental assessment prepared for a manufacturing license. The NRC is adding §§ 51.32(b)(3) and (4) to state the NRC's generic determination of no significant environmental impact associated with issuance of a final or amended manufacturing license. As with the parallel provisions governing design certifications in § 50.32(b)(1) and (2), the NRC is including an explicit statement of no significant environmental impact for manufacturing licenses in § 51.32(b)(3) and (4) to facilitate external stakeholder's understanding of the nature of the Commission's action. The NRC is

adding § 51.31(c) to describe the NRC's process for determining the manufacturing license with respect to environmental issues covered by NEPA.

The NRC is adding § 51.50(c)(3) to provide that if a combined license application proposes using a manufactured reactor, then the combined license environmental report may incorporate by reference the environmental assessment for the manufacturing license under which the reactor is to be manufactured and, if so, must include information demonstrating that the site characteristics for the combined license site fall within the site parameters specified in the manufacturing license environmental assessment. This section also states that the environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

Finally, the NRC is adding § 51.75(g) to indicate that if the proposed combined license application to use a manufactured reactor and the site characteristics of the combined license's site fall within the site parameters specified in the manufacturing license environmental assessment,¹¹ then the combined license EIS must incorporate by reference the manufacturing license environmental assessment. As in the case where the combined license application references a design certification, § 51.75(g) requires the combined license EIS to summarize the findings and conclusions of the environmental assessment with respect to SAMDAs. Finally, § 51.75(g) explicitly provides that the combined license EIS will not address the environmental impacts of manufacturing the reactor under the manufacturing license.

NEPA obligations associated with § 52.103(g) findings on ITAAC.

¹¹Analogous to design certifications, it is possible that an applicant for a manufacturing license may have chosen to specify site parameters for the manufacturing license safety review under § 52.79 which differ from the site parameters specified in the environmental report for its design. If the combined license application proposes to use such a manufactured reactor, then the combined license applicant must demonstrate that the two differing sets of site parameters are met, in order for the full division of issue finality provisions in § 52.171 to apply in the combined license proceeding.

Formerly, neither part 51 nor subpart C of part 52 explicitly addressed whether an environmental finding under NEPA is needed in connection with an NRC finding under § 52.103(g) that combined license ITAAC have been met. Nor does part 51 or subpart C of part 52 explicitly address whether contentions on environmental matters may be admitted in a hearing under § 52.103(b). The NRC never intended to make an environmental finding in connection with the § 52.103(g) finding on ITAAC, and the NRC does not believe that NEPA requires such a finding. The § 52.103(g) finding that ITAAC have been met is not a “major Federal action significantly affecting the environment.” The major Federal action occurs when the NRC issues the combined license, which includes the authority to operate the nuclear power plant—subject to an NRC finding of successful completion of ITAAC. This is the reason why the environmental impacts of operation under the combined license are evaluated and considered by the NRC in determining whether to issue the combined license even under the former provisions of part 52, see § 52.89. By contrast, the scope and nature of the NRC finding that ITAAC have been met is constrained by the ITAAC itself (indeed, the NRC has always recognized the possibility that ITAAC could be written such that the “inspections and tests” exception in Section 554(a)(3) of the APA could be invoked to preclude the need to provide an opportunity for hearing on § 52.103(g) findings). The safety consequences of operation are not considered when making the § 52.103(g) findings; these issues are addressed by the NRC in determining whether to issue the combined license in the first place. Therefore, the NRC does not view the § 52.103(g) finding as constituting a “major Federal action,” and makes no environmental findings in connection with that finding. It, therefore, follows that no contentions on environmental matters should be admitted in any hearing under § 52.103(b).

Accordingly, the NRC is adding § 51.108 to clarify that: (1) the Commission will not make any environmental findings in connection with the finding under § 52.103(g); and (2) contentions on any environmental matters, including the adequacy of the combined license

EIS and any referenced environmental assessment, may not be admitted into any § 52.103(b) hearing on compliance with ITAAC. Those issues are essentially challenges to the continuing validity of the combined license or any referenced design certification or manufacturing license. Accordingly, these challenges should be raised with the Commission using relevant Commission-established processes for requesting Commission action. A challenge on environmental grounds with respect to the combined license or manufacturing license must be filed under the provisions of § 2.206. A challenge to an existing design certification on environmental grounds must be filed as a petition for rulemaking to modify the existing design certification under subpart H of part 2.

NEPA Compliance for Combined Licenses Referencing an Early Site Permit

The NRC has made several changes in the final rule based on public comments regarding the requirements for a combined license application referencing an early site permit and further consideration of the NRC's obligations under NEPA for such actions. In the proposed rule, part 51 would have required the preparation on an EIS for all combined licenses referencing an ESP. Several commenters believed that an ESP and COL met the definition of "connected actions," under NEP case law and Council on Environmental Quality (CEQ) regulations, and should therefore not require the preparation of a new EIS for the second of the two connected actions, or a revalidation of previous findings if neither the applicant nor others identify new and significant information. Commenters stated that under applicable NEPA case law, there was no requirement to prepare a new EIS for the latter of the two connected actions that were previously evaluated together in a single EIS. The commenters stated that the EIS prepared at the ESP stage serves as the EIS for issuance of both the ESP and COL. Commenters stated that the ESP EIS included an evaluation of the environmental impacts

related to issuance of a COL inasmuch as it considered the environmental impact of plant construction and operation.

The NRC continues to believe that it is not necessary to require that all topics be covered in a single EIS at the ESP stage, and that topics such as alternative energy sources and need for power may be treated in an EIS supplement at the COL application stage when the detailed planning for the project is completed. As the commenters note, new and significant information may also prompt the preparation of a supplement to the ESP EIS in connection with the COL application. The NRC has modified the final rule to limit the preparation of a supplementary EIS to those situations. Since the NRC believes that some issues may not be ripe for consideration at the ESP stage, and an ESP EIS need not address such issues, the Commission is declining to take a position on whether the granting of an ESP and the granting of a COL referencing that ESP are connected actions. Nonetheless, if detailed planning and associated environmental information is in fact complete when an ESP application is filed, there is no bar to the NRC to prepare, at the ESP stage, an EIS that resolves all environmental matters associated with construction and operation of a power reactor at the ESP site, including the benefits of such construction and operation (*e.g.*, need for power), and alternative energy sources. The Commission may then rely on that EIS at the COL stage, provided that new and significant information has not been identified. The Commission need not label the ESP and COL as connected actions to adopt this procedure. Accordingly, the NRC has modified the final rule to allow for an ESP EIS to serve as the EIS for a COL application referencing the ESP without supplementation under such circumstances.

More specific changes to individual sections in part 51 are discussed as follows:

1. Section 51.20, *Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.*

The NRC is revising § 51.20(b) to identify the part 52 licensing processes that require an EIS or a supplement to an EIS. Specifically, the NRC is revising § 51.20(b)(1) to indicate that issuance of an early site permit requires an EIS. The NRC is revising § 51.20(b)(2) to indicate that issuance of a combined license requires an EIS, except as provided under § 51.75. Section 51.75(e) provides the criteria that must be met to issue a combined license without preparing an EIS. Also, paragraph (b)(6) is being removed and reserved because, under the Commission's proposed revision to the requirements for manufacturing licenses, only an environmental assessment is required at this stage.

2. Section 51.22, *Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.*

The NRC is revising § 51.22(c) to identify part 52 licensing processes that are eligible for categorical exclusion or otherwise do not require environmental review.

3. Section 51.23, *Temporary storage of spent fuel after cessation of reactor operation—generic determination of no significant environmental impact.*

The NRC is revising §§ 51.23(b) and(c) to indicate that the provisions of these paragraphs also apply to combined licenses.

4. Section 51.26, *Requirement to publish notice and conduct scoping process.*

The NRC is adding a new paragraph (d) to this section to provide requirements for publication of a notice of intent when the NRC determines that a supplement to an early site permit EIS will be prepared for a combined license referencing that early site permit. This new provision also states that, in such cases, the NRC staff need not conduct a scoping process, provided, however, that if scoping is conducted, then the scoping must be directed at matters to be addressed in the supplement as described in § 51.92. The NRC is also adding a provision in paragraph (d)(2) allowing the NRC to prepare a notice of intent before determining whether a supplement to an early site permit EIS will be prepared or whether an environmental assessment with a finding of no new and significant information will be prepared. This allowance will help avoid delays in the completion of the NRC's environmental review in the situation where the NRC determines that a supplemental EIS needs to be prepared based on new and significant information that is identified late in the review process

5. Section 51.27, *Notice of intent.*

The NRC is adding a new paragraph (b) to this section to provide requirements for the contents of a notice of intent when the NRC determines that a supplement to an early site permit EIS will be prepared for a combined license referencing that early site permit. Paragraph (b) states that the notice of intent will, among other things, describe the matters to be addressed in the supplement to the early site permit final EIS and describe any proposed scoping process that the NRC staff may conduct.

6. Section 51.29, *Scoping-environmental impact statement and supplement to environmental impact statement.*

The NRC is revising paragraph (a)(1) of this section in the final rule to include requirements for supplements to an early site permit EIS prepared for a combined license application.

8. Section 51.30, *Environmental assessment.*

The NRC is revising § 51.30 further in the final rule to include requirements for a combined license referencing an early site permit for which an environmental assessment is required under § 51.75(e). Specifically, the NRC is adding new paragraph (e) and redesignating proposed paragraph (e) as final paragraph (f). Paragraph (e) requires that an environmental assessment required by § 51.75(e) for a combined license referencing an early site permit with an EIS resolving all environmental issues must: (1) identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application; (2) reference the final environmental impact statement prepared for the early site permit; (3) include a discussion of the bases for the NRC's conclusion that there is no new and significant information with respect to the issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding; and (4) list the agencies and persons consulted, and identify the sources used.

9. Section 51.31, *Determinations based on environmental assessment.*

The NRC is revising § 51.31 in the final rule to provide requirements for environmental assessments leading to a determination of no new and significant information. Specifically, § 51.31 is revised to require that, upon completion of an environmental assessment for proposed actions other than those involving a standard design certification or a manufacturing license under part 52, the appropriate NRC staff director will determine whether to prepare an environmental impact statement, a finding of no significant impact, or a proposed finding of no new and significant information on the proposed action. This section also states that a draft finding of no new and significant information must be prepared and published for public comment.

10. Section 51.36, *Finding of no new and significant information*; § 51.37, *Draft finding of no new and significant information*; § 51.38, *Final finding of no new and significant information*; and § 51.39, *Publication of draft and final finding of no new and significant information*; *limitation on NRC action.*

The NRC is adding a new group of sections in the final rule, based on public comments, after § 51.35 under the new heading “Finding of No New and Significant Information.” Under this heading, the NRC is adding §§ 51.36, 51.37, 51.38, and 51.39 to clarify the NRC’s obligations under NEPA in the case where an early site permit EIS resolves all environmental issues related to the impacts of construction and operation of the proposed facility and there is no new and significant information identified at the combined license stage. In these sections, the NRC defines a new type of finding resulting from an environmental assessment that is

specific to this situation, *i.e.*, a finding of no new and significant information, and provides the requirements for publishing a draft finding for public comment.

In a change from the NRC's current NEPA practice, the finding of no new and significant information will be made directly by the Commission, and will not be delegated to a presiding officer. Thus, the notice and comment process for the environmental assessment and draft finding of no new and significant information, which is provided by § 51.37 and § 51.38, satisfies the Commission's obligations under NEPA, as well as the Section 189 of the AEA. Accordingly, the presiding officer is precluded from admitting any contentions into the combined license hearing concerning the adequacy of the environmental assessment or the correctness of the finding of no new and significant information. Moreover, the presiding officer is also precluded from making any findings of fact or conclusions of law in its initial decision which addresses those matters.

11. Section 51.45, *Environmental report.*

The NRC is revising § 51.45(c) to indicate that the analysis in an environmental report prepared for an early site permit need not include consideration of the economic, technical, and other benefits and costs of the proposed action and of energy alternatives. This change is being made for consistency with the provisions of § 51.50(b), which state that an environmental report included in an early site permit application need not include an assessment of the benefits (*e.g.*, need for power) of the proposed action and with the Commission's denial of a Petition for Rulemaking (See PRM-52-02 (October 28, 2003; 68 FR 55905)).

12. Section 51.50, *Environmental report—construction permit, early site permit, or combined license stage.*

The NRC is revising the title of § 51.50 to “Environmental report—construction permit, early site permit, or combined license stage,” and to including separate paragraphs with specific requirements for environmental reports for early site permit and combined license applications which are based on existing requirements in part 51 for construction permits and operating licenses and requirements for early site permits and combined licenses in part 52.

The NRC is revising the requirements from former § 52.17(a)(2) to clarify that an early site permit applicant has the flexibility of either addressing the matter of alternative energy sources in the environmental report supporting its early site permit application, or deferring consideration of alternative energy sources to the time that the early site permit is referenced in a licensing application. The NRC believes the former regulations already afforded the early site permit applicant such flexibility, inasmuch as former § 52.17(a)(2) stated that the environmental report submitted in support of an early site permit application must “focus on the environmental effects of construction and operation of a reactor, or reactors....” The environmental report’s discussion of alternative energy sources does not, *per se*, address the “environmental effects of construction and operation of a reactor,” which is one of the matters which must be addressed in an environmental impact statement (EIS). [See 10 CFR 51.71(d); National Environmental Policy Act of 1969 (NEPA), Sec. 102(2)(C)(i), (ii), and (v).] Rather, alternative energy sources constitute part of the discussion of reasonable alternatives to the proposed action, which is required by Section 102(2)(C)(iii) of NEPA. [See 10 CFR 51.71(e) n.4; 46 FR 39440 (August 3, 1981) (proposed rule that would eliminate consideration of need for power and alternative energy sources at operating license stage), at 39441 (first column) (final rule published March 26, 1982; 47 FR 12940).] See *Exelon Generation Company, LLC et al.*, CLI-05-17, 62 NRC 5, where the Commission ruled that:

[T]he “reasonable alternatives” issue does not apply with full force to ESP (or “partial” construction permit) cases. At the ESP stage of the construction permit process, the boards’ “reasonable alternatives” responsibilities are limited because the proceeding is focused on an appropriate *site*, not the actual construction of a reactor. Thus, boards must merely weigh and compare alternative sites, not other types of alternatives (such as alternative energy sources). (*Id.* at 48 (citations omitted))

Accordingly, the NRC believes that former § 52.17(a)(2) already provided the early site permit applicant the flexibility of choosing to defer consideration of alternative energy sources to the time that the early site permit is referenced in a combined license or a construction permit application. The revisions in § 51.50(b) clarify that the early site permit applicant may either include a discussion of alternative energy sources in its environmental report, or defer consideration of the matter. The NRC made conforming amendments elsewhere in part 51 to clarify that the NRC’s EIS need not address the need for power or alternative energy sources (and therefore these matters may not be litigated) if the early site permit applicant chooses not to address these matters in its environmental report. The environmental report and EIS for an early site permit must address the benefits associated with issuance of the early site permit (*e.g.*, early resolution of siting issues, early resolution of issues on the environmental impacts of construction and operation of a reactor(s) that fall within the site characteristics, and ability of potential nuclear power plant licensees to “bank” sites on which nuclear power plants could be located without obtaining a full construction permit or combined license). The benefits (and impacts) of issuing an early site permit must always be addressed in the environmental report and EIS for an early site permit, regardless of whether the early site permit applicant chooses to defer consideration of the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site. This is because the “benefits...of

the proposed action” for which the discussion may be deferred are the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site; the benefits which may be deferred are entirely separate from the benefits of issuing an early site permit. The proposed action of issuing an early site permit is not the same as the “proposed action” of constructing and operating a nuclear power plant for which the discussion of benefits (including need for power) may be deferred under §51.50(b).

The NRC is further modifying § 51.50(b) in the final rule based on public comments. This section addresses requirements for environmental reports at the early site permit stage. In the proposed rule, § 51.50(b) stated that environmental reports “must focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the postulated site parameters.” Commenters pointed out that the use of “postulated site parameters” was not consistent with the terminology the NRC had used elsewhere in the proposed rule. Consequently, the NRC is revising this provision in the final rule to require that the environmental report “must focus on the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application.” A similar change is being made to the same language in final rule § 51.75(b) [proposed § 51.71(d)].

The NRC is making additional changes to § 51.50(b) to further clarify the scope of the environmental review at the early site permit stage. Final § 51.50(b)(2) states that an early site permit environmental report may address one or more of the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, but that the environmental report must address all environmental effects of construction and operation necessary to determine whether there is any obviously superior alternative to the site

proposed. The purpose of this change is to clearly delineate that the scope of the environmental review at the early site permit stage is, at a minimum, to address all issues needed for the NRC to perform its evaluation of the alternative sites. In addition, the applicant may choose to address one or more issues related to construction and operation of the facility with the goal of achieving finality on those issues at the early site permit stage.

In addition, the NRC is modifying §§ 51.50(b) and 51.50(c) in the final rule to reflect comments made at the NRC's public workshops during the public comment period on the proposed rule. These discussions related to the requirement to include a proposed list of activities and a redress plan in license applications that request authority to perform activities under § 50.10(e). The NRC concluded that it is preferable to include both the list of proposed activities and the redress plan as separate documents in the application, outside of both the final safety analysis report (or site safety analysis report in the case of an early site permit) and the environmental report. The NRC's conclusion is based on the fact that the requirements in § 50.10(e) address both safety and environmental issues. Additional changes were made to §§ 52.17(c), 52.79(a), and 52.80 to implement this concept.

The NRC is also revising § 51.50(c) based on public comments in the final rule. These revisions address the situation where a combined license applicant is referencing an early site permit and provide for a clearer link to the finality provisions in § 52.39, eliminate language that attempted to define "new and significant," and provide greater consistency with related requirements elsewhere in part 51. The revisions also provide requirements for addressing environmental terms and conditions. The discussion that follows reflects the language in the final rule.

The NRC is adding a requirement in § 51.50(c)(1) that the applicant's environmental report need not contain information or analyses submitted to the Commission in the early site permit environmental report or resolved in the Commission's early site permit environmental

impact statement, but must contain, in addition to the environmental information and analyses otherwise required: (1) information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit; (2) information to resolve any significant environmental issue that was not resolved in the early site permit proceeding; (3) any new and significant information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding; (4) a description of the process used to identify new and significant information regarding the NRC's conclusions in the early site permit environmental impact statement, including a requirement that the process use a reasonable methodology for identifying such new and significant information; and (5) a demonstration that all environmental terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the combined license.

The NRC's regulations and the applicable case law interpreting the National Environment Policy Act of 1969, as amended (NEPA), support the NRC staff's belief that, inasmuch as an early site permit and a combined license are major Federal actions significantly affecting the quality of the human environment, both actions require the preparation of an EIS. However, 10 CFR part 52 does provide finality for previously resolved issues. Under NEPA, the combined license environmental review is informed by the EIS prepared at the early site permit stage and the NRC staff intends to incorporate the early site permit EIS by reference in the combined license EIS. The combined license applicant must address any other significant environmental issue not considered in any previous proceeding, such as issues deferred from the early site permit stage to the combined license stage (e.g., the benefits assessment).

For an early site permit, the NRC prepares an EIS that resolves numerous issues within certain bounding conditions. These issues have issue preclusion at the combined license, CP or OL stage provided certain conditions are met. A combined license, CP, or OL application

must demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit. In addition, the application must include any new and significant information for issues related to the impacts of construction and operation of the facility (*i.e.*, the issue being addressed at the combined license stage) that were resolved in the early site permit proceeding. Documentation related to the applicant's search for new information and its determination about the significance of the new information should be maintained in an auditable form by the applicant. While the NRC is ultimately responsible for completing any required NEPA review under 10 CFR 51.70(b), for example, an evaluation of the impact of new and significant information on the conclusions for a resolved early site permit environmental issue, the combined license applicant must identify whether there is new and significant information on such an issue. A combined license applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form. The NRC staff will verify that the applicant's process for identifying new and significant information is effective.

The NRC staff, in the context of a combined license application that references an early site permit, has defined the term "new" in the phrase "new and significant information" as any information that was both (1) not considered in preparing the ESP environmental report or EIS (as may be evidenced by references in these documents, applicant responses to NRC requests for additional information, comment letters, etc.) and (2) not generally known or publicly available during the preparation of the EIS (such as information in reports, studies, and treatises). For new information to be "significant," it must be material to the issue being considered, *i.e.*, it must have the potential to affect the NRC staff's evaluation of the issue. The COL applicant need only provide information about a previously resolved environmental issue if it is both new and significant.

The combined license applicant referencing an early site permit is also required to provide information sufficient to resolve any other significant environmental issue not considered in the early site permit proceeding (*e.g.*, need for power) and the information contained in the application should be sufficient to aid the staff in its development of an independent analysis (see 10 CFR 51.45).

Finally, the combined license applicant referencing an early site permit must demonstrate that all environmental terms and conditions included in the early site permit will be satisfied by the date of issuance of the combined license. In some cases, this may require adding a condition to the combined license to adequately address the environmental issue raised in the early site permit condition. Note that this provision was added to § 51.50(c)(1) in the final rule. Requirements to include environmental conditions in an early site permit environmental report were addressed in the proposed rule in § 51.50(b), but the associated provision to ensure any conditions included in the permit would be met was inadvertently left out of § 51.50(c)(1).

In the past, the NRC staff has attempted to explain the relationship between the environmental review of an early site permit application to that of a combined license application referencing the early site permit by analogy to the license renewal environmental review process. The NRC staff believes the analogy especially useful because the license renewal process is well-established and clearly understood. Because there appears to be some confusion regarding this analogy, NRC believes a brief explanation of the similarities of the two processes is warranted.

For license renewal, the NRC prepared a generic EIS (GEIS) that resolved more than 60 issues for all plants based on certain bounding assumptions. These were termed Category 1 issues. If a license renewal applicant identifies new and significant information with respect to a Category 1 issue, it documents its assessment of that information in its application.

If the applicant determines that this new information is not significant, or that there is no new information, the applicant documents the bases for these determinations in an auditable form and makes the documentation available for staff inspection. If there is new and significant information on a Category 1 issue, the NRC staff limits its inquiry to determine if this information changes the Commission's earlier conclusion set forth in the GEIS. The NRC staff may inquire if the applicant has a reasonable process for identifying new and significant information on Category 1 issues.

Similarly, in the NRC environmental review process for a combined license application, the combined license EIS brings forward the Commission's earlier conclusions from the early site permit EIS and articulates the activities undertaken by the NRC staff to ensure that an issue that was resolved can remain resolved. If there is new and significant information on a previously resolved issue, then the staff will limit its inquiry to determine if the information changes the Commission's earlier conclusion. Environmental matters subject to litigation in a combined license proceeding mainly include (1) those issues that were not considered in the previous proceeding on the site or the design; (2) those issues for which there is new and significant information; and (3) those issues subject to the change or exemption processes in 10 CFR part 52.

Notwithstanding that, in the context of renewal, the GEIS resolves Category 1 issues through rulemaking and an early site permit resolves environmental issues through an individual licensing proceeding, the staff believes that the license renewal practice is similar to the part 52 process in which a combined license application references an early site permit.

The NRC staff has determined that a combined license is a major Federal action significantly affecting the quality of the human environment and, in accordance with 10 CFR 51.20, the NRC must prepare an EIS on that action. If there is no new and significant information for matters resolved at the ESP stage, then the staff will rely upon ("tier off") the

early site permit EIS and disclose the NRC conclusion for matters covered in the early site permit review. Such matters will not be subject to litigation at the combined license stage.

13. Section 51.51, *Uranium fuel cycle environmental data—Table S-3.*

The NRC is revising § 51.51 to require that every environmental report prepared for the early site permit stage or combined license stage of a light-water-cooled nuclear power reactor use Table S-3, Table of Uranium Fuel Cycle Environmental Data, as the basis for evaluating the contribution of the environmental effects of the uranium fuel cycle to the environmental costs of licensing light-water cooled nuclear power reactors. If the application for a combined license references an early site permit in which the environmental impacts and costs related to the uranium fuel cycle were already evaluated and resolved, then the repetition of this information in the environment report for the combined license is not required unless the applicant has identified new and significant information regarding these environmental impacts and costs.

14. Section 51.52, *Environmental effects of transportation of fuel and waste—Table S-4.*

The NRC is revising § 51.52 to require that every environmental report prepared for the early site permit stage or combined license stage of a light-water-cooled nuclear power reactor contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. If the application for a combined license references an early site permit in which the transportation of fuel and radioactive wastes to and from the reactor has already been evaluated and resolved, then the repetition of this information in the environment report for the

combined license is not necessary unless the applicant has identified new and significant information regarding the associated environmental impacts.

15. Section 51.53, *Postconstruction environmental reports.*

The NRC is revising § 51.53(a) to clarify that any postconstruction environmental report may incorporate by reference any information contained in a prior environmental report or supplement thereto that relates to the site or any information contained in a final environmental document previously prepared by the NRC staff that relates to the site. This change reflects the recognition that environmental documents will be prepared at the early site permit stage and may be referenced in environmental documents for future licensing actions. The NRC is also revising § 51.53(a) to clarify that documents that may be referenced in post construction environmental reports include those prepared in connection with an early site permit or a combined license. In addition, the NRC is revising § 51.53(c)(3) to clarify that the requirements for the content of environmental reports submitted in applications for renewal of a combined license are the same as those for renewal of an operating license.

16. Section 51.54, *Environmental report—manufacturing license.*

The NRC is revising this section by adding two paragraphs to delineate the difference in the matters with respect to SAMDAs that must be addressed in an environmental report for issuance of a manufacturing license under subpart F of part 52, versus that for an amendment to the manufacturing license. Section 51.54(a) provides that the environmental report for the manufacturing license must address the costs and benefits of SAMDAs, and the bases for not incorporating into the design of the manufactured reactor any SAMDAs identified during the

applicant's review. Section 51.54(b) reflects the narrower scope of a environmental report submitted in connection with a proposed amendment to a manufacturing license, by providing that the report need only address whether the design change which is subject of a proposed amendment either renders a SAMDA previously identified and rejected to become cost beneficial, or results in the identification of new SAMDAs that may be reasonably incorporated into the design of the manufactured reactors.

As discussed earlier, the environmental impacts of manufacturing a reactor under a manufacturing license are not considered by the NRC, and § 51.54 indicates that the environmental report need not include a discussion of the environmental impacts of manufacturing a reactor.

17. Section 51.55, *Environmental report—standard design certification.*

The NRC is transferring the provisions in current § 51.55 to a new § 51.58 (discussed in § 51.58), and the NRC is revising this section to address the contents of environmental reports for design certifications under subpart B of part 52. The structure of new § 51.55 is similar to that of § 51.54, reflecting the fact that the environmental review for either manufacturing licenses or design certifications is limited to SAMDAs. Section 51.55(a) provides that the environmental report for the design certification must address the costs and benefits of SAMDA, and the bases for not incorporating into the design certification any SAMDAs identified during the applicant's review. Section 51.55(b) provides that the environmental report submitted in support of a request to amend a design certification, need only address whether the design change which is the subject of a proposed amendment either renders a SAMDA previously identified and rejected to become cost beneficial, or results in the identification of new SAMDAs that may be reasonably incorporated into the design certification.

18. Section 51.58, *Environmental report—number of copies; distribution.*

The matters previously addressed in § 51.55 are addressed in a new § 51.58. The NRC is adding conforming references to § 51.58(a) for early site permits and combined licenses. Section 51.58(b) contains a conforming reference to subpart F of part 52.

19. Section 51.71, *Draft environmental impact statement—contents.*

The NRC is revising § 51.71(d) to include a reference to § 51.75 in the first sentence because § 51.75 also includes exceptions to the provisions in § 51.71(d). This represents a change the NRC is making in the final rule to move the specific discussions on early site permits and combined licenses from § 51.71(d) to their associated paragraphs in § 51.75. The NRC is also revising associated footnote 3 to include references to early site permits and combined licenses.

20. Section 51.75, *Draft environmental impact statement—construction permit, early site permit, or combined license.*

The NRC is adding §§ 51.75(b), (c), and (d) and a new Footnote 5 to include separate requirements for the preparation of draft EISs at the early site permit and combined license stages. In the final rule, the NRC is also moving information related to early site permits that was contained in proposed § 51.71(d) to § 51.75(b). In addition, the NRC is providing further clarification in the final rule on the scope of the environmental review at the early site permit stage. Final § 51.75 requires that the draft environmental impact statement must include an

evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed. The draft environmental impact statement must also include an evaluation of the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, but only to the extent addressed in the early site permit environmental report or otherwise necessary to determine whether there is any obviously superior alternative to the site proposed. The purpose of this change is to clearly delineate that the scope of the environmental review at the early site permit stage is, at a minimum, to address all issues needed for the NRC to perform its evaluation of the alternative sites. In addition, the applicant may choose to address one or more issues related to construction and operation of the facility with the goal of achieving finality on those issues at the early site permit stage. The NRC also notes that, where the early site permit application identifies a specific nuclear power reactor design (*i.e.*, a standard design certification or manufacturing license) under § 52.17(a)(1)(i), the environmental report for an early site permit may address the applicability of the severe accident mitigation design alternatives (SAMDA) evaluation for that reactor design to the proposed site. In this situation, the early site permit EIS must determine whether the site characteristics bound the site parameters relevant to the SAMDA analysis, as specified in the environmental assessment for the identified nuclear power reactor design.

The requirements for combined licenses are organized into separate paragraphs (c), (d), (e), (f), and (g) which address the contents of the combined license environmental impact statement if the combined license application references an early site permit or standard design certification, or proposes to use a manufactured reactor. For example, § 51.75(g) provides that the combined license EIS will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

In the final rule, the NRC is moving information related to combined licenses that was contained in proposed § 51.71(d) to § 51.75(d) and (e) and is revising the wording of this provision. In the proposed rule, § 51.71(d) stated that the draft supplemental environmental impact statement prepared at the combined license stage when an early site permit is referenced need not include detailed information or analyses that were resolved in the final environmental impact statement prepared by the Commission in connection with the early site permit, provided that the design of the facility falls within the design parameters specified in the early site permit, the site falls within the site characteristics specified within the early site permit, and there is no new and significant environmental issue or information not considered on the site or the design only to the extent that they differ from that discussed in the final environmental impact statement prepared by the Commission in connection with the early site permit. In the final rule, the NRC has added new paragraphs (d) and (e) which replace proposed paragraph (c)(1). Paragraph (d) addresses combined license applications referencing an early site permit with an EIS with unresolved environmental issues. Paragraph (e) addresses combined license applications referencing an early site permit with an EIS that resolves all environmental issues. The language in these paragraphs provides a clearer link to the finality provisions in § 52.39, eliminates language in the proposed rule that attempted to define “new and significant,” and provides greater consistency with related requirements elsewhere in part 51. In the final rule, § 51.75(d)(1) states that a supplement to the early site permit EIS for the combined license application will be prepared if: (1) the final EIS prepared in connection with the early site permit does not disclose the economic, technical or other benefits (for example, need for power) and costs of the proposed action or does not set forth an evaluation of alternative energy sources; (2) there is a significant environmental issue related to the impacts of construction or operation of the facility that was not previously resolved in the proceeding on the early site permit; or (3) there is new and significant information identified with

respect to issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding. Paragraph (d)(2) requires that the supplement be prepared in accordance with § 51.92. This language is consistent with the language in § 51.50(c)(1) regarding what must be included in an combined license applicant's environmental report that references an early site permit and it is consistent with the final rule language in § 52.39(c)(1)(v) regarding finality of environmental information.

Paragraph (e)(1) states that a finding of no new and significant information for a combined license application referencing an early site permit will be prepared only if: (1) the final EIS prepared in connection with the early site permit discloses the economic, technical or other benefits (for example, need for power) and costs of the proposed action, contains an evaluation of alternative energy sources and resolves all environmental issues related to the impacts of construction and operation of the facility; and (2) there is no new and significant information identified with respect to issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding. Paragraph (e)(2) requires that the finding of no new and significant information be prepared in accordance with § 51.36. These changes are consistent with other changes made in part 51 in the final rule to reflect NRC's determination that it is not necessary to require that all topics be covered in a single EIS at the ESP stage and that topics such as alternative energy sources and need for power may be treated in an EIS supplement at the COL application stage. On the other hand, if detailed planning and associated environmental information is in fact complete when an ESP application is filed, there is no bar to the NRC to prepare, at the ESP stage, an EIS that resolves all environmental matters associated with construction and operation of a power reactor at the ESP site, including the benefits of such construction and operation (*e.g.*, need for power), and alternative energy sources.

21. Section 51.92, *Supplement to the final environmental impact statement.*

The NRC is revising § 51.92 in the final rule to provide requirements for NRC staff preparation of a supplement to the final environmental impact statement for an early site permit when the permit is referenced in a combined license application as required by § 51.75(d). Specifically, a supplement to an early site permit final environmental impact statement must:

- (1) identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application;
- (2) incorporate by reference the final environmental impact statement prepared for the early site permit;
- (3) contain no separate discussion of alternative sites;
- (4) include an analysis of the economic, technical, and other benefits and costs of the proposed action, to the extent that the final environmental impact statement prepared for the early site permit did not include an assessment of these benefits and costs;
- (5) include an analysis of other energy alternatives, to the extent that the final environmental impact statement prepared for the early site permit did not include an assessment of energy alternatives;
- (6) include an analysis of any environmental issue related to the impacts of construction or operation of the facility that was not previously resolved in the proceeding on the early site permit; and
- (7) include an analysis of the issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding for which new and significant information has been identified, including, but not limited to, new and significant information demonstrating that the design of the facility falls outside the site characteristics and design parameters specified in the early site permit.

22. Section 51.95, *Postconstruction environmental impact statements.*

The NRC is revising § 51.95(a) to indicate that documents that may be referenced in a supplement to a final environmental impact statement include documents prepared in connection with an early site permit or combined license. In addition, the NRC is revising § 51.95(c) to correct the address for the NRC Public Document Room. The NRC is revising § 51.95 to indicate that the NRC will prepare a supplemental environmental impact statement in connection with the amendment of a combined license authorizing decommissioning activities or with the issuance, amendment, or renewal of a license to store spent fuel at a nuclear power reactor after expiration of the combined license, and that the supplement may incorporate by reference any information contained in the final environmental impact statement for the combined license or in the records of decision prepared in accordance with an early site permit or combined license. Finally, the NRC is revising § 51.95(d) to indicate that, unless otherwise required by the Commission, in accordance with the provisions of § 51.23(b), a supplemental environmental impact statement for the post combined license stage will address the environmental impacts of spent fuel storage only for the term of the license, amendment, or renewal applied for.

23. Section 51.105, *Public hearings in proceedings for issuance of construction permits or early site permits.*

The NRC is revising the section heading and § 51.105(a) to indicate that the requirements for presiding officers in public hearings on construction permits also apply to public hearings on early site permits. In addition, the NRC is adding § 51.105(b) to indicate that the presiding officer in an early site permit hearing shall not admit contentions concerning the benefits assessment (*e.g.*, need for power), or alternative energy sources if the applicant did not address those issues in the early site permit application. This change is being made for

consistency with the provisions of § 51.50(b), which state that an environmental report included in an early site permit application need not include an assessment of the benefits (e.g., need for power) of the proposed action, and with the Commission's denial of a Petition for Rulemaking (See PRM-52-02 (October 28, 2003; 68 FR 55905)). The NRC notes that the environmental report and EIS for an early site permit must address the benefits associated with issuance of the early site permit (e.g., early resolution of siting issues, early resolution of issues on the environmental impacts of construction and operation of a reactor(s) that fall within the site characteristics, and ability of potential nuclear power plant licensees to "bank" sites on which nuclear power plants could be located without obtaining a full construction permit or combined license). The benefits (and impacts) of issuing an early site permit must always be addressed in the environmental report and EIS for an early site permit, regardless of whether the early site permit applicant chooses to defer consideration of the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site. This is because the "benefits...of the proposed action" for which the discussion may be deferred are the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site; the benefits which may be deferred are entirely separate from the benefits of issuing an early site permit. The presiding officer needs to be mindful of whether the applicant has addressed only the benefits of issuing the early site permit or whether the applicant has also addressed all of the benefits of construction and operation of the facility. This is because the presiding officer, in accordance with § 51.105(a)(3), must determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the early site permit should be issued, denied, or appropriately conditioned to protect environmental values. If the applicant has addressed all of the costs and benefits associated with construction and

operation of the facility in its environmental report, the final balancing between costs and benefits needs to occur at the early site permit stage.

The NRC also notes that, where the early site permit application identifies a specific nuclear power reactor design (*i.e.*, a standard design certification or manufacturing license) under § 52.17(a)(1)(i), the environmental report for an early site permit may address the applicability of the severe accident mitigation design alternatives evaluation for that reactor design to the proposed site. In this situation, the early site permit EIS must determine whether the site characteristics bound the site parameters relevant to the SAMDA analysis, as specified in the environmental assessment for the identified nuclear power reactor design. In addition, in accordance with Section 52.107(d), the presiding officer shall not admit contentions proffered by any party concerning severe accident mitigation design alternatives unless the contention demonstrates that the site characteristics fall outside of the site parameters in the standard design certification or underlying manufacturing license for the manufactured reactor.

24. Section 51.105a, *Public hearings in proceedings for issuance of manufacturing licenses.*

The NRC is adding § 51.105a to provide requirements for public hearings in proceedings for issuance of manufacturing licenses. Specifically, § 51.105a establishes that the presiding officer in a proceeding for the issuance of a manufacturing license will (1) determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate to identify all reasonable SAMDAs for the design of the reactor to be manufactured, and evaluate the environmental, technical, economic, and other benefits and costs of each SAMDA; and (2) determine, in a contested proceeding, whether the manufacturing license should be issued as proposed by the appropriate NRC staff director.

25. Section 51.107, *Public hearings in proceedings for issuance of combined licenses.*

The NRC is adding § 51.107 to set out the requirements for public hearings in proceedings for issuance of combined licenses. The requirements parallel the associated requirements for public hearings on construction permits and operating licenses, as appropriate, and provide requirements unique to the combined license process that are derived from various provisions in part 52, namely §§ 52.39 and 52.103. The NRC is making changes to the language in § 51.107 in the final rule to more clearly define the role of the presiding officer in a proceeding for the issuance of a combined license where an early site permit is being referenced. Specifically, paragraph (b) addresses the situation where a combined license application references an early site permit and a supplement to the early site permit environmental impact statement is prepared in accordance with § 51.75(d) and § 51.92(e). In such cases, the presiding officer in the combined license hearing shall not admit any contention proffered by any party on environmental issues which have been accorded finality under § 52.39 unless the contention: (1) demonstrates that the nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit; (2) raises any significant environmental issue that was not resolved in the early site permit proceeding; or (3) raises any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which new and significant information has been identified.

Paragraph (c) addresses the situation where a combined license application references an early site permit and a finding of no new and significant information is prepared in accordance with § 51.75(e) and § 51.36. As discussed earlier, the Commission is removing the determination of no new and significant information from the hearing process, and is reserving

to itself the final determination in this matter. Accordingly, the presiding officer in the combined license hearing shall not admit any contention proffered by any party on environmental issues which have been accorded finality under § 52.39. This includes any contention that the NRC incorrectly concluded that there is no new and significant information. In addition, the presiding officer also shall not make any findings with respect to the adequacy of the environmental assessment or the finding of no new and significant information.

26. Section 51.119, *Publication of finding of no significant impact, or no new and significant information; distribution.*

The NRC is revising paragraphs (a) and (b) of § 51.119 in the final rule to address requirements for publication and distribution of a finding of no new and significant information.

27. Section 51.120, *Availability of environmental documents for public inspection.*

The NRC is revising § 51.120 to provide requirements for the availability of findings of no new and significant information.

N. Changes to 10 CFR Part 54.

1. Section 54.1, *Purpose.*

This part applies to renewed operating licenses for nuclear power plants. A conforming change is made to this section to include renewed combined licenses.

2. Section 54.3, *Definitions.*

The definition for *renewed combined license* is added to explain the meaning of the new phrase as it is used in this part.

3. Section 54.17, *Filing of application.*

Section 54.17(c) is revised to add a conforming reference to combined licenses issued under 10 CFR part 52.

4. Section 54.27, *Hearings.*

This section is revised to include a conforming reference to renewed combined license issued under 10 CFR part 52.

5. Section 54.31, *Issuance of a renewed license.*

Sections 54.31(a), (b), and (c) are revised to include conforming references to combined licenses in this procedure on issuance of renewed licenses.

6. Section 54.35, *Requirements during term of renewed license.*

This section is revised to include conforming references to holders of combined licenses and the regulations in part 52 into the requirements for a renewed license.

7. Section 54.37, *Additional records and recordkeeping requirements.*

Section 54.37(a) is revised to include a conforming reference to a renewed combined license.

O. Changes to 10 CFR Part 55.

Part 55 establishes the NRC's requirements for licensing of operators of utilization facilities in accordance with the statutory requirements in Section 202 of the ERA. Formerly, the provisions in part 55 referred only to utilization facilities licensed under part 50, and therefore, do not address utilization facilities licensed for operation under a combined license issued under subpart C of part 52. Section 202 of the ERA, however, does not limit its mandate to operators of facilities licensed under part 50; the statutory requirement would also appear to apply to operators of facilities licensed under part 52 (*i.e.*, combined licenses under subpart C of part 52).

Accordingly, §§ 55.1 and 55.2 are revised by adding a reference to part 52. This clarifies that each operator of a nuclear power reactor licensed under a part 52 combined license or renewed under part 54 must first obtain an operator's license under part 55. In addition, the conforming changes clarify that these operators, as well as holders of combined licenses issued under part 52 or renewed under part 54, are subject to the requirements in part 55 (*e.g.*, part E of part 55, *Written Examinations and Operating Tests*, set forth requirements which are directed, for the most part, at the holders of operating licenses for utilization facilities).

P. Changes to 10 CFR Part 72.

1. Section 72.210, *General license issued.*

Part 72 sets forth the requirements for independent spent fuel storage facilities. This section is revised to include a conforming reference to persons authorized to operate nuclear power reactors under 10 CFR part 52 (*i.e.*, a combined license holder).

2. Section 72.218, *Termination of licenses.*

Section 72.218(b) is revised to include a conforming reference to combined licenses issued under part 52.

Q. Changes to 10 CFR Part 73.

Part 73 establishes the NRC's requirements for the physical protection of production and utilization facilities licensed by the NRC. It provides requirements for the physical protection of licensed activities, for personnel access authorization, and for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information. Formerly, the language of § 73.1, *Purpose and scope*, § 73.2, *Definitions*, § 73.50, *Requirements for physical protection of licensed activities*, § 73.56, *Personnel access authorization requirements for nuclear power plants*, and § 73.57, *Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information by power reactor licensees*, and Appendix C,

Licensee Safeguards Contingency Plans, did not refer to combined licenses issued under part 52. However, part 73 was formerly applicable to combined licenses under the provisions of § 52.83, *Applicability of part 50 provisions*, which states that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses. Accordingly, § 73.1 is revised to clarify that the regulations in part 73 apply to persons who receive combined licenses under part 52, and § 73.2 is revised to state that terms defined in part 52 have the same meaning when used in part 73. The NRC has addressed combined licenses in § 73.57 by making the provisions that are required before receiving an operating license under part 50 applicable before the date that the Commission makes the finding under § 52.103 for a combined license. Additional conforming changes to include part 52 licenses are made for §§ 73.50 and 73.56, and appendix C to part 73.

R. Change to 10 CFR Part 75.

1. Section 75.6, *Maintenance of records and delivery of information, reports, and other communications.*

Part 75 sets forth NRC requirements intended to implement the agreement between the United States and the International Atomic Energy Agency (IAEA) with respect to safeguards of nuclear material. Various provisions throughout part 75 require certain licensees and other individuals and entities regulated by the NRC to submit to the NRC various reports and communications. Section 75.6 specifies the NRC officials to whom these reports and communications are to be sent. However, § 75.6(b) - the provision applying to, *inter alia*, nuclear power plants - refers only to holders of a construction permit or an operating license,

and does not include holders of combined licenses. Accordingly, § 75.6(b) is revised to reference combined licenses. The NRC notes that early site permits and manufacturing licenses need not be referenced, inasmuch as the U.S.-IAEA Safeguards Agreement does not extend to early site permits or manufacturing licenses.

S. Changes to 10 CFR Part 95.

The following discussion explains the requirements in part 95 generically and covers §§ 95.5, 95.13, 95.19, 95.20, 95.23, 95.31, 95.33 through 95.37, 95.39, 95.43, 95.45, 95.49, 95.51, 95.53, 95.57, and 95.59.

Part 95 sets forth the NRC requirements governing what individuals and entities may be provided access to National Security Information (NSI) and/or Restricted Data (RD) received or developed in connection with activities licensed, certified, or regulated by the NRC, and how this information and data is to be protected by these individuals and entities against unauthorized disclosure.

Although requirements for protection of NSI and RD must, by statute, apply to all individuals and entities provided access to such information, various sections in part 95 use slightly different wording to delineate the relevant set of individuals and entities. To ensure consistency, the Commission is revising its regulations to refer to “licensee, certificate holder, or other person,” to describe the individuals and entities subject to the applicable requirements. In adopting this phrase, the NRC intends to ensure that its regulatory requirements for protection of NSI and RD in part 95 extend as broadly as the NRC’s authority provided under applicable law. The term, “licensee,” includes both holders of all NRC licenses, including (but not limited to) combined licenses, as well as holders of permits such as construction permits and early site permits. The term, “certificate holder,” includes (but is not limited to) all certificates of approval

that the Commission may issue, such as a certificate of compliance for spent fuel casks under 10 CFR part 72. Finally, the term, “or other person,” is intended to include individuals and entities who are subject to the regulatory authority of the Commission, including applicants for standard design approvals and standard design certifications under part 52. For the same reasons, the Commission is revising § 95.39 to use the phrase, “NRC license, certificate, or standard design approval or standard design certification under part 52.”

T. Changes to 10 CFR Part 140.

Part 140 addresses the NRC requirements applicable to nuclear reactor licensees with respect to financial protection and indemnity agreements to implement Section 170 of the AEA, commonly referred to as the Price-Anderson Act. In general, the indemnification and financial protection requirements in part 140 become applicable when a holder of a 10 CFR part 50 construction permit who also possesses a materials license under 10 CFR part 70 brings fuel onto the site. However, part 140 did not address the indemnification and financial protection requirements of combined license holders. Accordingly, the final rule revises various sections in part 140 to address combined licenses under part 52.

The NRC does not believe that part 140 must be revised to address any part 52 licensing process other than a combined license. Neither an early site permit nor a manufacturing license authorizes the possession or use of nuclear fuel or other nuclear materials, and the NRC would not issue these licenses with a materials license under part 70. The NRC also believes that part 140 need not be revised to address standard design approvals or standard design certifications, because neither of these processes authorize the possession or use of nuclear fuel or other nuclear materials.

U. Changes to 10 CFR Part 170.

Part 170 sets out the fees charged for licensing services performed by the NRC. The NRC is revising § 170.2(g) and (k) to add conforming references to manufacturing licenses and standard design approvals issued under part 52, add a reference to appendix Q to part 50 (in addition to the existing reference to appendix Q to part 52), and delete the reference to a manufacturing license issued under part 50 (which is being removed from part 50 because of its transfer to part 52 in the 1989 rulemaking adopting part 52).

V. Changes to 10 CFR Part 171.

Part 171 sets out the annual fees charged to persons who hold licenses issued by the NRC. The NRC is revising § 171.15 to add conforming references to combined licenses issued under part 52. Note that for combined licenses, the requirements of part 171 are not applicable until after the Commission has made the finding under § 52.103(g). This section also provides fee requirements for each person holding a part 50 power reactor license that is in decommissioning or possession only status and each person holding a part 72 license who does not hold a part 50 license. The NRC also added conforming changes to include references in part 52 in these provisions.

VI. Section-by-Section Analysis

Part 52, General Provisions

§ 52.0 Scope; applicability of 10 CFR Chapter 1 provisions.

This section, formerly designated as § 52.1, has been expanded to: (1) address all licensing and regulatory processes covered in part 52; and (2) more clearly define the relationship between part 52 and remaining provisions of 10 CFR Chapter 1. Paragraph (a), which establishes the scope of part 52, is revised by referring to all licensing and regulatory processes covered in part 52. In addition, paragraph (a) is revised to give notice to contractors, subcontractors or consultants of applicants for or holders of licenses or regulatory approvals under part 52 that they are subject to NRC enforcement action for violations of the deliberate misconduct proscriptions in § 52.4. The Commission notes, as discussed below in the section-by-section analysis of § 52.4, that deliberate misconduct under § 52.4 may occur as the result of a violation of any Commission rule and regulation throughout 10 CFR Chapter 1, not just a violation of a requirement in part 52.

Paragraph (b) is a new provision that supersedes former § 52.83. The first sentence of paragraph (b) is intended to make clear that the Commission's regulations in 10 CFR Chapter 1 apply to applicants and holders of licenses, permits and other regulatory approvals in part 52 (e.g., design approvals and standard design certifications). Accordingly, applicants, licensees and holders of regulatory approvals under part 52 should review the regulations in 10 CFR Chapter 1 to ensure that they are in compliance with applicable Commission requirements throughout 10 CFR Chapter 1. The second sentence of paragraph (b) reinforces the applicability of the Commission's requirements throughout 10 CFR Chapter 1 to part 52 licenses, permits, and other regulatory approvals. As part of this final rule, the Commission is making conforming changes as necessary throughout Chapter 1 to ensure that relevant regulations clearly set forth their applicability to part 52 licenses and approvals, and to part 52 entities such as applicants, licensees, and holders. Nonetheless, the Commission is adopting

paragraph (b) in order to clearly and unambiguously impose applicable regulatory requirements that exist throughout 10 CFR Chapter 1.

§ 52.1 Definitions.

This section, formerly designated as § 52.2, has been supplemented by: (1) adding definitions of terms that are used in part 52 but were undefined in the previous rule; and (2) providing definitions of new terms that were added in this rulemaking to provide greater clarity and precision. New definitions which are noteworthy are discussed individually as follows.

A definition of *modular design* is added to explain the type of modular reactor design to which the Commission intended to refer to in the second sentence of the current § 52.103(g). This special provision for modular designs was added to part 52 to facilitate the licensing of nuclear plants, such as the Modular High Temperature Gas-Cooled Reactor (MHTGR) and Power Reactor Innovative Small Module (PRISM) designs, that consisted of three or four nuclear reactors in a single power block with a shared power conversion system. During the period that the power block is under construction, the Commission could separately authorize operation for each nuclear reactor when each reactor and all of its necessary support systems were completed. The Commission believes that the term “modular design” needs to be defined to aid future use of the current § 52.103(g) by distinguishing the intended definition from other currently used definitions for “modular design.” Also, future combined license applicants for a multi-unit site that would be similar to current multi-unit sites (where each unit is similar in design but independent of all other units) could use this provision.

Definitions of the terms *design characteristics*, *design parameters*, *site characteristics*, and *site parameters* were added to § 52.1 to clarify their meaning and use in the licensing and

approval processes of part 52. *Design characteristics* are defined as the actual features of a nuclear reactor or reactors. Design characteristics are specified in the final safety analysis report for a standard design approval, a standard design certification, a combined license application, or a manufacturing license. *Design parameters* are defined as the postulated features of a nuclear reactor or reactors that could be built at the proposed site. Design parameters are specified in an early site permit application. *Site characteristics* are defined as the actual physical, environmental, and demographic features of a site. Site characteristics are specified in an early site permit or combined license application. *Site parameters* are defined as the postulated physical, environmental, and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or manufacturing license.

The values for the characteristics and parameters will be used in the NRC's review of combined license applications that reference design approvals, design certifications, manufacturing licenses, or early site permits. For example, § 52.79(b) requires that a combined license application referencing an early site permit contain information sufficient to demonstrate that the actual design characteristics of the nuclear facility fall within the design parameters and site characteristics specified in the early site permit. Also, § 52.79(d) requires that a combined license application referencing a design certification rule must contain information sufficient to demonstrate that the actual site characteristics fall within the site parameters specified in the design certification.

The above terms are also used in §§ 52.39 and 52.93. Because the NRC is relying on certain design parameters specified in the early site permit applications to reach its conclusions on site suitability, these design parameters will be included in any early site permit issued. The NRC believes that its review of a combined license application that references an early site permit will involve a comparison to ensure that the actual characteristics of the design chosen

by the combined license applicant fall within the design parameters specified in the early site permit. A combined license application that references a design certification will involve a comparison to ensure that the actual characteristics of the site chosen by the combined license applicant fall within the site parameters in the design certification. Similarly, if a combined license applicant references both an early site permit and a design certification, the NRC will review the application to ensure that the site characteristics in the early site permit fall within the site parameters in the referenced design certification and that the actual design characteristics fall within the design parameters in the early site permit.

A new definition of *major features of the emergency plans* is added to explain what aspects of emergency preparedness - short of full and integrated emergency plans - an early site permit applicant may seek approval of under § 52.17(b)(2)(i). A major feature may consist of a specific aspect of a plan necessary to address in whole or part 1 or more of the 16 planning standards in 10 CFR 50.47(b). Additional requirements for each of the planning standards are set forth in part 50, appendix E, and the applicant may choose to demonstrate compliance with one or more provisions in appendix E, either in addition to or without a full demonstration of compliance with a planning standard in § 50.47(b), when seeking approval of *part* of a major feature. A major feature may also be a description of one or both of the emergency planning zones (EPZs) required by 10 CFR 50.33(g). Regulatory considerations governing EPZs are set forth in § 50.33(g); a major feature need not address all of these considerations.

A definition of *prototype plant* is added to explain the type of nuclear power plant that the Commission intended in the former § 52.47(b) (new § 50.43), and § 52.157(e)). A prototype plant is a licensed nuclear reactor test facility that is similar to and representative of either the first-of-a-kind or standard nuclear plant design in all features and size, but may have additional safety features. The purpose of the prototype plant is to perform testing of new or innovative

safety features for the first-of-a-kind nuclear plant design, as well as being used as a commercial nuclear power facility.

§ 52.2 Interpretations.

This section, formerly designated as § 52.5, remains unchanged. It provides that the only interpretations of part 52 that are legally binding on the Commission are interpretations provided by the General Counsel. These written interpretations, which are rarely provided by the General Counsel, are set forth in 10 CFR part 8.

§ 52.3 Written communications.

This new section, which is analogous to § 50.4, sets forth administrative requirements regarding written communications with the NRC, including the addressing of such communications, and listings of the various NRC offices and officials who must receive copies of different types of communications (*e.g.*, applications for licenses and license amendments, security plan and related submissions, quality assurance related submissions). The administrative requirements themselves are identical to those in § 50.4; they are reproduced in § 52.3 to make clear that they apply to applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52.

§ 52.4 Deliberate misconduct.

This section, formerly designated as § 52.9, has been substantially rewritten in order to more clearly delineate the applicability of the proscriptions against deliberate misconduct to all delineated part 52 entities, including applicants for and holders of standard design approvals, and applicants for standard design certifications (including those applicants whose designs are certified by the Commission in a standard design certification rulemaking). Although the regulatory language in § 52.4 differs from former § 52.9, no substantive change in any aspect of the Commission law or the underlying policy considerations is being made by the Commission's adoption of § 52.4. The relevant law and policy considerations for former § 52.9 are merely clarified and extended in § 52.4 to cover applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52.

§ 52.5 Employee protection.

This new section, which is analogous to § 50.7, prohibits discrimination against employees for engaging in protected activities established in Section 211 of the Energy Reorganization Act of 1974, as amended (1974 ERA). These protected activities, which are listed in § 52.5(a)(1), include (but are not limited to) providing the Commission or the employer information about alleged violations of the AEA or 1974 ERA, of any of the Commission's regulations. No substantive change in any aspect of the Commission law or the underlying policy considerations with respect to employee protection is being made by the Commission adoption of § 52.5; the relevant law and policy considerations for former § 50.7 are merely clarified and extended in § 52.5 to cover applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52 (currently, standard design approvals and standard design certifications). In addition, the final rule provides that the Commission may impose civil penalties on contractors and subcontractors of licensees and applicants.

§ 52.6 Completeness and accuracy of information.

This new section, which is analogous to § 50.9, requires that all information submitted to the NRC by the delineated part 52 entities be complete and accurate, and imposes a reporting requirement on such entities with respect to information with respect to the regulated activity having a significant implication for public health and safety or common defense and security. No substantive change in any aspect of the Commission law or the underlying policy considerations is being made by the Commission adoption of § 52.6; the relevant law and policy considerations underlying § 50.9 are merely clarified and extended to cover applicants for and holders of permits, licenses and regulatory processes that are contained in part 52. For example, § 50.9 does not impose a positive obligation on licensees to seek out new information meeting the reporting thresholds in the rule. In applying § 52.6, the Commission would extend this interpretation to part 52 entities such as combined license holders and standard design certification applicants (including applicants whose applications were approved, for the regulatory life of the certification rule).

§ 52.7 Specific exemptions.

This new section, which is analogous to § 50.12, provides for specific procedures and criteria for Commission grants of exemptions from the provisions of part 52. No substantive change in any aspect of the Commission law or the underlying policy considerations is being made by the Commission adoption of § 52.7; the relevant law and policy considerations underlying § 50.12 are merely extended to part 52.

The NRC notes that the exemption provisions in § 52.7 do not supercede or otherwise diminish more specific exemption provisions that are in part 52, such as the provision of a

specific design certification rule or § 52.63(b)(1) governing exemptions from one or more elements of a design certification rule. An applicant or licensee referencing a standard design certification rule who wishes to obtain an exemption from one or more elements must meet the criteria in the specific design certification rule or § 52.63(b)(1). If the applicant or licensee is unable to demonstrate compliance with those criteria, then it may request an exemption under the more encompassing authority of § 52.7. However, the exemption request must then demonstrate compliance with the additional criteria in § 52.7.

The Commission also notes that § 52.7 does not supercede the applicability of more specific dispensation provisions in other parts of Chapter 1. For example, a holder of a combined license would not require a separate part 52 exemption in order to obtain approval of an alternative to a provision of an applicable ASME Code provision that is otherwise required under 10 CFR 50.55a; the licensee need only satisfy the criteria in § 50.55a(a)(3). However, in the absence of a more specific dispensation provision, the Commission intends to utilize § 52.7 as a means for granting dispensation from compliance with Commission requirements in other parts of 10 CFR Chapter 1. The person requesting an exemption need only address the § 52.7 criteria as applied to the underlying requirement for which dispensation from compliance is sought, and need not also address dispensation from compliance with the relevant part 52 requirement. For example, the holder of the combined license who wishes dispensation from compliance with a fire protection requirement in 10 CFR 50.48 need only address the relevant criteria in § 52.7 with respect to the reasons for dispensation from compliance with § 50.48. The holder need not address dispensation from compliance with § 52.0, which otherwise makes applicable the provisions of § 50.48 on the licensee. Any exemption granted by the Commission would address the reasons for dispensation with the underlying requirement - in this case, § 50.48, and would also provide dispensation from compliance with § 52.0.

§ 52.8 Combining licenses; elimination of repetition.

This new section includes provisions analogous to §§ 50.31, 50.32, and 50.52 and is added to clarify that these regulatory provisions also apply to part 52 licenses. Paragraph (a), which is analogous to § 50.31, is added to make clear that an applicant for a license under part 52 may combine in one application, several applications for different kinds of licenses under various regulations in 10 CFR Chapter 1. Section 50.31 currently provides that an applicant may combine in one application, several applications for different kinds of licenses under various regulations in 10 CFR Chapter 1. The plain reading of this language, given that this provision is located in part 50, is that a *part 50* application may contain in one application other applications for different licenses in other parts of 10 CFR Chapter 1. Thus, § 50.31 would not appear to allow a *part 52* application (as for a combined license) to combine in one application other applications for different license in other parts of 10 CFR Chapter 1. Accordingly, paragraph (a) makes clear that a part 52 application may be combined with application for different licenses in other parts of 10 CFR Chapter 1.

Paragraph (b), which is analogous to § 50.32, is added to make clear that an applicant for a license, standard design certification, or design approval under part 52 may incorporate by reference in its application information contained in other documents provided to the Commission, but that such incorporation must clearly specify the information to be incorporated.

Paragraph (c), which is analogous to § 50.52, is added to clarify the Commission's authority under Section 161.h of the AEA to combine NRC licenses, such as a special nuclear materials license under part 70 for the reactor fuel, with a combined license under part 52. Analogous to the situation with respect to § 50.31, the language in § 50.52 would not appear to allow the Commission to combine into a single part 52 license, other non-part 52 licenses. No substantive change in any aspect of the Commission law or the policy considerations underlying

§§ 50.31, 50.32, and 50.52 is being made by the Commission adoption of § 52.8; the relevant law and policy considerations underlying §§ 50.31, 50.32, and 50.52 are merely extended to part 52.

§ 52.9 Jurisdictional limits.

This new section, which is analogous to § 50.53, makes clear that no approval provided by the Commission under part 52 addresses or approves in any manner activities which are not under or within the territorial jurisdiction of the United States. As a practical matter, this means that an approval or license issued by the NRC under part 52 has no legal effect outside the territorial jurisdiction of the United States. No substantive change in any aspect of the Commission law or the policy considerations underlying § 50.53 is being made by the Commission adoption of § 52.9; the relevant law and policy considerations are merely extended to part 52.

§ 52.10 Attacks and destructive acts.

This new section, which is analogous to § 50.13, applies the existing Commission law and policy that a licensee need not provide for design features or other measures to protect against certain attacks and destructive acts, or the use or deployment of weapons incident to U.S. defense activities, to the applicants for and holders of permits, licenses and other approvals under part 52. No substantive change in any aspect of the Commission law or the underlying policy considerations is being made by the Commission adoption of § 52.10; the relevant law and policy considerations for the § 50.13 exclusion are merely extended to cover

applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52.

§ 52.11 Information collection requirements: OMB approval.

This section, formerly designated as §52.8, remains unchanged. It gives notice that all information collection and reporting requirements in part 52 have been approved by the Office of Management and Budget. No requirement, action or responsibility is imposed on part 52 entities by this section.

Subpart A – Early Site Permits

§ 52.12 Scope of subpart.

This section describes the scope of this licensing process. Under this subpart an applicant can request pre-approval of a site (so-called site banking), separate from other licensing actions, and subsequently reference that early site permit in a future application to build a nuclear power plant. This process was created for proposed sites that the applicant may not plan to use in the near term.

§ 52.13 Relationship to other subparts.

This section explains the relationship of the early site permit process to the construction permit process under 10 CFR part 50 and to the combined license process under part 52. An

applicant who plans to use the proposed site in the near-term and has selected siting issues to resolve could request early review of such site suitability issues in accordance with appendix Q to part 52.

§ 52.15 Filing of applications.

This section explains who can file, how to file, and the fees for NRC review of an application for an early site permit.

§ 52.16 Contents of applications; general information.

This section sets forth the type of general information that is required to be included in an early site permit application, namely, the information required by 10 CFR 50.33(a) through (d) and (j). Section 50.33 requires that the application include information such as the name and address of the applicant, a description of the business or occupation of the applicant, and citizenship information of the applicant. Section 50.33 also provides requirements for the handling of Restricted Data or other defense information in an application.

§ 52.17 Contents of applications; technical information.

The purpose of this section is to set forth the type of technical information to be included in an application for an early site permit. Paragraph (a)(1) identifies the information needed for the site safety review, excluding emergency planning information. The site safety information is a subset of the information required of applicants for construction permits. Although an ESP

applicant does not need to specify a particular nuclear plant design, as in construction permit applications, it does need to provide sufficient surrogate design information (developed to bound the nuclear plant design(s) that are being considered by the applicant) so that the NRC can make a determination on the acceptability of the site and the environmental impacts, and determine whether designs bounded by the surrogate design information provided by the applicant can be qualified for the proposed site. The application must contain, among other things, the specific number, type (e.g., pressurized-water reactor), and thermal power level of the facilities, or range of possible facilities, for which the site may be used; the anticipated maximum levels of radiological and thermal effluents each facility will produce; the type of cooling systems, intakes, and outflows that may be associated with each facility; the boundaries of the site; and the proposed general location of each facility on the site. As part of the description of the proposed general location of each facility on the site (52.17(a)(1)(v)), the applicant should describe the foot print for all structures and external safety-related design features proposed for the site.

The application must also include the seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated. This information is to ensure that future plants built at the site would be in compliance with General Design Criterion 2 from appendix A to part 50, which requires that structures, systems, and components important to safety be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunamis, and seiches without loss of capability to perform their safety functions.

The application must also include the location and description of any nearby industrial, military, or transportation facilities and routes, and the existing and projected future population

profile of the area surrounding the site. The application must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site from a radiological safety standpoint. In addition, the application must demonstrate that adequate security plans and measures can be developed for the site and must provide a description of the quality assurance program applied to site-related activities.

Paragraph (a)(2) identifies that the application must include an environmental report that meets the requirements of § 51.50(b). Environmental reports must focus on the environmental effects of construction and operation of a nuclear reactor, or reactors, which have characteristics that fall within the design parameters postulated in the early site permit. Environmental reports must also include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed. Environmental reports submitted in an early site permit application are not required to but may include an assessment of the economic, technical, and other benefits and costs of the proposed action or an analysis of other energy alternatives.

Paragraph (b) identifies the emergency planning information to be included in the application. All ESP applicants are required to identify in the site safety analysis report (SSAR) physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans, *e.g.*, a physical characteristic or combination of physical characteristics that could pose major difficulties for evacuation or the taking of other protective actions. In addition, if the applicant identifies such physical characteristics, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. After meeting this mandatory requirement, paragraph (b) allows applicants the option of either submitting major features of emergency plans or complete and integrated emergency plans for approval by the NRC, in consultation with the Department of Homeland

Security (DHS). For complete and integrated emergency plans, the applicant must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC's regulations. The inclusion of such inspections, tests, analyses, and acceptance criteria (ITAAC) is necessary to allow the NRC to make the finding that the plans submitted by the applicant provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Paragraph (b) also allows applicants proposing major features of emergency plans to include proposed ITAAC. Where the applicant is submitting a complete and integrated emergency plan, a utility plan must be submitted if any offsite agencies elect not to participate in the development of emergency planning information.

If the applicant plans to perform the preparations for construction activities identified in 10 CFR 50.10(e)(1), then paragraph 52.17(c) requires the applicant to describe the activities it is requesting to perform and propose a redress plan that, if carried out, would achieve a "self-maintaining, environmentally stable, and aesthetically acceptable site" that conforms to local zoning laws. Redress plans are expected to be modeled on the redress requirements imposed on the Clinch River Breeder Reactor project (see *In the Matter of the U.S. Department of Energy, et al*, LBP-85-7, 21 NRC 507 (1985)). By containing a redress plan, the ESP will constitute assurance that, if site preparation activities are conducted but the site is never used for a nuclear power plant, the site will be returned to an acceptable and stable condition.

§ 52.18 Standards for review of applications.

This section identifies the regulations that the NRC staff will use in performing its review of an application for an early site permit, including the standards that the NRC staff will use in performing its assessment of emergency preparedness information provided in the ESP application.

§ 52.21 Administrative review of applications; hearings.

This section identifies the procedural requirements that apply to the mandatory hearing for the early site permit licensing process. This section also clarifies that the applicant's environmental report is not required to but may include an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources. In addition, the presiding officer in an ESP hearing is prohibited from admitting contentions on these matters if those issues were not addressed in the early site permit application.

§ 52.23 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

This section states that the ACRS will report on those portions of the application which concern safety which is the same role the ACRS had with respect to construction permits in the past.

§ 52.24 Issuance of early site permit.

The purpose of this section is to set forth the timing of issuance of an ESP and the findings that the Commission must make to issue the ESP, including that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public, that the applicant is technically qualified to engage in activities necessary to prepare the ESP application and any site preparation activities that the applicant is seeking approval to perform, and that the findings required by subpart A of 10 CFR part 51 regarding the NRC staff's assessment of the environmental impact have been made.

This section also requires that the early site permit specify the site characteristics, design parameters, and terms and conditions of the early site. Before issuance of either a construction permit or a combined license referencing an early site permit, the Commission must find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions that could not be met by the time of issuance of the construction permit or combined license must be set forth as terms or conditions of the construction permit or combined license. Finally, this section requires that the early site permit specify the site preparation activities under § 52.17(c) that the permit holder is authorized to perform.

§ 52.25 Extent of activities permitted.

This section specifies that, if the construction preparation activities authorized by § 52.24(c) are performed and the site is not referenced in a application for a construction permit or a combined license while the permit remains valid, then the early site permit remains in effect for the purpose of site redress with the goal of achieving an environmentally stable and aesthetically acceptable site.

§ 52.27 Duration of permit.

The purpose of paragraph (a) of this section is to specify the duration of an early site permit. The applicant can request a duration of up to 20 years and the Commission will determine the duration of the ESP based, in part, on the quality and reliability of the site information that is provided to support the ESP application. Paragraph (b) describes the conditions under which an ESP can continue to be valid beyond its expiration date. Paragraph (c) allows an applicant for a construction permit or combined license, at its own risk, to reference an ESP that is under review by the NRC but not yet granted. Paragraph (d) explains that, upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license. By “subsumed” the NRC means that the information that was contained in the early site permit SSAR becomes part of the referencing combined license FSAR upon issuance of the combined licenses in the same manner as if the combined license applicant had not referenced an early site permit. The NRC is including the phrase “to the extent referenced,” to indicate that it is not all of the information submitted in the early site permit application that is subsumed into the combined license, but, rather, only that information that is contained in the SSAR and identified by the applicant as being referenced in the combined license application. This subsumption of the early site permit into the referencing license affects the way changes to the early site permit information will be handled because it breaks the tie to the finality provisions in § 52.39. After issuance of the construction permit or combined license, § 52.39 no longer applies to the early site permit information and such information will be covered by the same finality provisions as the rest of the information in the FSAR (with the exception of any referenced design certification information), as outlined in § 52.98 (e.g., in accordance with §§50.54, 50.59, etc.).

§ 52.28 Transfer of early site permit.

This section specifies the requirements to be followed if a holder of an early site permit wants to transfer the ESP to another person or company.

§ 52.29 Application for renewal.

Paragraph (a) of this section explains the contents and timing of an application for renewal of an early site permit. Paragraph (b) sets forth the procedure for requesting a hearing on the application for renewal. Paragraph (c) explains that an ESP may remain in effect beyond its expiration under certain circumstances. Specifically, an ESP for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the permit. If an ESP is not renewed, it continues to be valid in any proceeding on an application for a construction permit or a combined license which references the ESP and was docketed prior to the expiration of the ESP. Finally, paragraph (d) identifies the responsibilities of the ACRS on an ESP renewal application.

§ 52.31 Criteria for renewal.

Paragraph (a) of this section sets forth the criteria for granting a renewal of an early site permit and provides that, if the NRC wants to impose new requirements, it must demonstrate that the new requirements meet the backfit standard from § 50.109. Paragraph (b) explains that even if an application for renewal of an ESP is denied by the NRC, the applicant can submit a new application for an ESP that corrects the problems with the application for renewal.

§ 52.33 Duration of renewal.

This section specifies the duration of a renewed early site permit. An ESP may, upon application, be extended for periods of up to 20 years beyond the previously approved duration, provided the criteria in § 52.31 are met.

§ 52.35 Use of site for other purposes.

The purpose of this section is to explain how the holder of an early site permit could use the site for other activities. An approved site may be used for purposes not related to the construction of a nuclear power facility, *e.g.*, a fossil-fueled station or a park, provided that the Commission is informed of all significant non-nuclear uses prior to actual construction or site modification activities. A permit may be revoked if a non-nuclear use would interfere with a nuclear use, or would so alter the site that important assumptions underlying the issuance of the permit were called into question.

§ 52.39 Finality of early site permit determinations.

This section specifies the special backfit requirements that apply to an early site permit. Paragraph (a) provides requirements regarding finality of ESP issues as they relate to the Commission. Paragraph (a)(1) states that, notwithstanding any provision in 10 CFR 50.109 (Backfitting), while an early site permit or renewed early site permit is in effect, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission meets one of four conditions. Those conditions are that the Commission either determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was

issued; determines that a modification is necessary to assure adequate protection of the public health and safety or the common defense and security; determines that a modification is necessary based on an update under § 52.39(b); or issues a variance requested under § 52.39(d).

Paragraph (a)(2) addresses the finality of an early site permit for a license that references the early site permit and requires that the Commission treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in §§ 52.39(b), (c), and (d). This paragraph also addresses finality of changes to an early site permit approved emergency plan (or major features thereof).

Paragraph (b) requires a license applicant that references an ESP to update and correct the emergency preparedness information that was provided in the ESP and to discuss whether the new information materially changes the bases for compliance with the applicable NRC requirements. New information which materially changes the bases for compliance includes: (1) information which substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, and (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness, in accordance with § 52.39(a)(1). New information which materially changes the Commission's determination of the matters in § 52.17(b), or results in modifications of existing terms and conditions by the NRC under § 52.39(a)(1) would be subject to litigation during the licensing proceedings in accordance with § 52.39(c).

Section 52.39(c) provides requirements for the submittal of contentions in a proceeding for the issuance of a license referencing an early site permit and for the filing of petitions requesting that an early site permit be modified, suspended, or revoked. Paragraph (c)(1) states that contentions on several matters may be litigated in the proceeding on a combined

license that references an early site permit. Matters that may be litigated include contentions related to the following: (1) the nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit; (2) one or more of the terms and conditions of the early site permit have not been met; (3) a variance requested under § 52.39(d) is unwarranted or should be modified; (4) new or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for Commission to modify or impose new terms and conditions related to emergency preparedness; or (5) any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified. An issue related to the impacts of construction and operation of the facility resolved in the early site permit proceeding is afforded finality at the combined license stage provided that there is no “new and significant” information on the issue. If an environmental issue was not resolved at the early site permit stage, either because information was not sufficient to resolve it or because the early site permit applicant was permitted to defer it (*e.g.*, need for power analysis), then the combined license applicant would need to address the issue in its combined license application. The NRC, in the context of a combined license application that references an early site permit, has defined the term “new” in the phrase “new and significant information” as any information that was both (1) not considered in preparing the ESP environmental report or EIS (as may be evidenced by references in these documents, applicant responses to NRC requests for additional information, comment letters, etc.) and (2) not generally known or publicly available during the preparation of the EIS (such as information in reports, studies, and treatises). This new information may or may not be significant. For an issue to be significant, it must be material to the issue being considered, *i.e.*, it must have the potential to affect the NRC

staff's evaluation of the issue. The COL applicant need only provide information about a previously resolved environmental issue if it is both new and significant.

Paragraph (c)(2) allows any person to file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit be modified, or that the permit be suspended or revoked. The petition will be considered in accordance with § 2.206. Section 2.206 provides that any person may file a request to institute a proceeding to modify, suspend, or revoke a license, or for any other action as may be proper. Section 52.39(c)(2) addresses the Commission's required action on such a petition and states that construction under the construction permit or combined license will not be affected by the granting of the petition unless the Commission makes the order immediately effective.

Paragraph (d) provides that an applicant for a license or an amendment to such a license who has filed an application referencing an early site permit may request a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the SSAR. This paragraph also states that, once a construction permit or combined license referencing an early site permit is issued, a variance from the early site permit will not be granted for that construction permit or combined license. At that point, the early site permit is subsumed into the combined license and any request for a change to the terms or conditions of the combined license is a request for a license amendment that must be filed under the provisions of § 50.90.

The NRC is adding new paragraph (e) in the final rule in response to public comments expressing support for adding provisions to provide an early site permit holder with the option of requesting an amendment to the early site permit in order to resolve issues that were not addressed in the original early site permit review or to achieve finality on updated early site permit information. Paragraph (e) states that the holder of an early site permit may not make changes to the early site permit, including the SSAR, without prior Commission approval. The

request for a change to the early site permit must be in the form of an application for a license amendment, and must meet the requirements of 10 CFR 50.90 and 50.92. The NRC considers an early site permit SSAR to be equivalent to a combined license FSAR; therefore, when an early site permit is amended, the SSAR must be revised consistent with the ESP amendments. In addition, the SSAR retains continuing viability for early site permits that are for multiple units after it is referenced in the first combined license. However, unlike an FSAR, there is no change process for the SSAR that does not require NRC review and approval.

Finally, the Commission is adding a new paragraph (f) (proposed paragraph (e)) to the “finality” section in each subpart of part 52, including § 52.39, entitled “Information requests,” which delineates the restrictions on the NRC for information requests to the holder of the early site permit. This provision is analogous to the former provision on information requests in paragraph 8 of appendix O to parts 50 and 52, and is based upon the language of § 50.54(f). For early site permits, this provision is contained in § 52.39(f), and requires the NRC to evaluate each information request on the holder of an early site permit to determine that the burden imposed by the information request is justified in light of the potential safety significance of the issue to be addressed in the information request. The only exceptions would be for information requests seeking to verify compliance with the current licensing basis of the early site permit. If the request is from the NRC staff, the request would first have to be approved by the Executive Director for Operations (EDO) or his or her designee.

Subpart B - Standard Design Certifications

§ 52.41 Scope of subpart.

This section describes the scope of this licensing process for certification of standard nuclear power plant designs. Under this subpart, an applicant may request pre-approval of either an evolutionary light-water or advanced nuclear power plant design, separate from a site review or other licensing action, and subsequently reference that certified design in an application to build a nuclear power plant. The requirements for the type of plant to be certified were moved from § 52.45 to this section. The scope of the standard plant design must be essentially complete as described in § 52.47(c).

§ 52.43 Relationship to other subparts.

The purpose of this section is to explain the relationship of the design certification process to the processes set forth in subparts C, E, and F of 10 CFR part 52, which provide for combined licenses, standard design approvals, and manufacturing licenses. The requirement to hold a final design approval under former appendix O to part 52 as a prerequisite to design certification was deleted from § 52.45. However, applicants for design certification have the option of also applying for a standard design approval under subpart E. Also, applicants for a manufacturing license may reference a certified design.

§ 52.45 Filing of applications.

This revised section is similar to the “filing of applications” sections in subparts A and C of this part. This section explains how to file an application for design certification and how the fees for NRC’s review of the application will be assessed. Because design certification is a rule and not a license, the applicant for design certification does not need to be a U.S. citizen or company (AEA, Section 103).

§ 52.46 Contents of applications; general information.

This is a new section and it is similar to the “general information” sections in subparts A and C of this part. It identifies the general information that must be included in all applications.

§ 52.47 Contents of applications; technical information.

The purpose of this section is to identify the technical information that must be included in an application for design certification. This section was revised to provide a comprehensive list of requirements for a design certification application. Paragraphs (a) and (c) describe the information that must be included in the FSAR, which is included in the application, and paragraph (b) describes the information that must also be included in the application but does not need to be included in the FSAR. Paragraph (c) describes additional requirements for particular types of applications. This section also specifies the level of detail for the design information that must be provided in an application.

Many of the requirements in this section were taken from 10 CFR 50.34 or are pointers to technical requirements in parts 20, 50, 51, and 73 that must be addressed in the application. The requirements taken from § 50.34 are a subset of the information required of applicants for construction permits and operating licenses. Other requirements came from the original version of 10 CFR 52.47 or were developed by the Commission during the initial design certification reviews (e.g., SECY-93-087, ML003708021).

Although an applicant for design certification does not need to specify a particular site for the nuclear power plant, as in a combined license application, it does need to identify the site parameters, under paragraph (a)(1), that the standard nuclear power plant is designed to meet, e.g., postulated values for the safe-shutdown earthquake response spectra and

maximum tornado wind speed. These parameters are usually selected to envelop a large portion of existing nuclear plant sites in the United States. Once the design is certified by the NRC, conformance of the actual site with the established site parameters must be demonstrated by the applicant for a combined license and verified by the NRC when the application is submitted.

Paragraph (a)(7) requires the applicant for design certification to describe its qualifications to design and analyze a standard nuclear power plant, which may become part of the bases for a future license.

Paragraph (a)(13) requires the applicant to provide the electric equipment list required by § 50.49(d). The NRC understands that the applicant may not be able to establish qualification files for all applicable components.

In its staff requirements memorandum (SRM), dated February 15, 1991, on SECY-90-377, "Requirements for Design Certification under 10 CFR Part 52," the Commission directed the staff to ensure that the design certification process preserves operating experience insights in the certified design. In order to implement this requirement, paragraph (a)(22) requires the applicant to demonstrate how relevant operating experience insights from NRC's generic letters and bulletins, issued after the most recent revision of the applicable standard review plan, have been incorporated into the plant design. Operating experience includes consideration of operating events and the reliability and performance of structures, systems, and components. Regarding the requirement to address comparable international operating experience, the NRC understands that some future applications may be for designs that are not based on or evolutions of plant designs that have operated in the United States. Those applications should address how insights from relevant international operating experience have been incorporated into the plant design.

In its SRMs, dated June 26, 1990, and July 21, 1993, on SECY-90-16, "Evolutionary Light-Water Reactor Certification Issues and their Relationship to Current Regulatory Requirements," and SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Designs," respectively, the Commission approved NRC staff recommendations for selected preventative and mitigative design features for future light-water reactor designs. Paragraph (a)(23) requires the applicant to provide a description and analysis of those design features discussed in SECY-90-16 and SECY-93-087. Postulated severe accidents are not design-basis accidents (DBAs) and the severe accident design features do not have to meet the requirements for DBAs. However, the severe accident design features are part of a plant's design bases information.

Paragraph (a)(24) requires the applicant to provide a conceptual design for those design features that are outside the scope of the certified design, *e.g.*, service water intake structure or ultimate heat sink.

Paragraph (a)(25) requires the applicant to describe the interface requirements for those design features that are outside the scope of the certified design, *e.g.*, service water intake structure or ultimate heat sink. Paragraph (a)(26) requires justification that the interface requirements can be verified with the ITAAC for the plant.

Paragraph (a)(27) requires the applicant to provide a description of the design-specific PRA and its results. Guidance on how to meet the PRA information requirement will be provided in separate regulatory guidance documents.

Paragraph (b)(1) requires the applicant to provide the ITAAC that are necessary and sufficient to demonstrate that a facility that references the design certification has been constructed and will operate in conformity with the design certification, the Atomic Energy Act of 1954, as amended, and the Commission's regulations. These ITAAC will be a part of the Commission's verification program and must cover all of the design information that is within the

scope of the certified design. ITAAC for the remaining design features that are outside of the scope of the certified design will be provided in a combined license application that references the design certification rule.

In its SRM on SECY-91-229, "Severe Accident Mitigation Design Alternatives for Certified Standard Designs," dated October 25, 1991, the Commission approved the staff's recommendation that design certification applicants assess SAMDAs for their standard plant designs. The Commission required SAMDA evaluations in order to achieve greater finality for the design features that are resolved in design certification rulemakings. For further explanation, see discussion in SECY-93-087, dated April 2, 1993. In order to implement this requirement, paragraph (b)(2) requires the applicant to provide a SAMDA evaluation for the standard plant design. This assessment is distinct from, and in addition to, the requirement in paragraph (a)(23) to provide a description and analysis of severe accident design features.

Paragraph (c)(1) requires an essentially complete scope of design in applications for evolutionary nuclear power plants. These plants are improved versions of light-water reactor designs that were in operation when part 52 was originally codified. Examples of evolutionary designs include General Electric's U.S. Advanced Boiling Water Reactor and Westinghouse's SP/90 and System 80+ designs. Evolutionary designs do not have to meet the design qualification testing requirements set forth in 10 CFR 50.43(e).

Paragraph (c)(2) requires applications for "advanced" nuclear power plants to provide an essentially complete scope of design and meet the design qualification testing requirements in 10 CFR 50.43(e). Advanced designs differ significantly from evolutionary light-water reactor designs or incorporate, to a greater extent than evolutionary designs do, simplified, inherent, passive, or other innovative means to accomplish their safety functions. Examples of advanced nuclear power plant designs include General Atomic's Modular High Temperature Gas-Cooled Reactor, General Electric's Simplified Boiling Water Reactor, and Westinghouse's AP600.

Paragraph (c)(3) requires applications for modular nuclear power plant designs to describe and analyze the various options for configuration of multi-reactor nuclear power plants. Modular nuclear power plant designs are defined in § 52.1. Modular plant designs are not portions of a single nuclear plant, rather they are separate nuclear power reactors with some shared or common systems.

§ 52.48 Standards for review of applications.

This section sets forth the parts of 10 CFR that contain applicable requirements for the technical review of design certification applications. The applicability of these requirements to the design certification process is specified in the identified parts. The Commission recognizes that new designs may incorporate design features that are not addressed by the current standards set out in 10 CFR parts 20, 50 and its appendices, 51, 73, or 100, and that new standards may be required to address these new design features. The Commission will determine whether additional rulemakings are needed or appropriate to resolve generic safety issues that are applicable to multiple designs. On the other hand, new design features that are unique to a particular design could be addressed in the design certification rulemaking for that particular design.

§ 52.51 Administrative review of applications.

This section sets forth the procedures for performing a notice and comment rulemaking for design certification. Paragraph (b) states that the Commission will determine, at its sole discretion, whether to hold a legislative hearing on the proposed design certification rule under the procedures in subpart O of 10 CFR part 2. Paragraph (c) states that proprietary information

contained in an application for design certification will be given the same treatment that such information would be given in a proceeding on an application for a construction permit or an operating license under 10 CFR part 50. This gives the design certification applicant (vendor) an opportunity to treat elements of its design as trade secrets.

§ 52.53 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

This section states that the application for design certification shall be sent to the ACRS for its review of safety issues.

§ 52.54 Issuance of standard design certification.

Paragraph (a) of this section sets forth the findings that the Commission must make in order to issue a design certification rule. Paragraph (b) requires that site parameters, design characteristics, and any additional requirements and restrictions be specified in the design certification rule. Previous DCRs set forth the additional requirements and restrictions in Section IV of the rule. Site parameters and design characteristics are defined in § 52.1 and can be specified in the design control document. These values will be used during the review of a combined license application that references the design certification rule to verify that the standard plant design conforms with the characteristics of the actual site and the design parameters used in the early site permit.

Section 52.54 was amended to include a new paragraph (c) which requires that every DCR contain a provision stating that, after the Commission has adopted the final DCR, the applicant for that design certification will not permit any individual to have access to, or any facility to possess, Restricted Data or classified National Security Information until the individual

and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The NRC believes that this amendment, along with the changes to parts 25, 95, and § 50.37, are necessary to ensure that access to classified information is adequately controlled by all entities applying for NRC certifications.

§ 52.55 Duration of certification.

The purpose of this section is to specify the duration that a standard design certification is valid for referencing in a combined license application.

§ 52.57 Application for renewal.

The purpose of this section is to set forth the process for applying for renewal of an existing design certification rule. Paragraph (a) specifies the time period for submitting an application for renewal and states that any person can apply for renewal. However, if the applicant for renewal is not the same person or entity that applied for the existing design certification, as identified in Section I of the DCR, then the new applicant is required to demonstrate that they have the capability to provide the detailed design for that certified nuclear power plant under § 52.63(c) or § 52.73(b).

§ 52.59 Criteria for renewal.

The purpose of this section is to identify the regulations that will be used to determine if an existing design certification should be renewed. Paragraph (a) states that the Commission

will grant a request for renewal if the design complies with the regulations in effect at the time the certification was originally issued (see Section V of an existing design certification rule) and imposition of any new safety requirements on the design during a renewal proceeding will be governed by the backfit standards in paragraph (b).

Under paragraph (c), the applicant for renewal may request an amendment to the existing certified design to make some design changes provided that the new design meets the regulations in effect at the time that the amended, renewed design certification rule is issued and the changes do not require a major review or reanalysis of the new design. If the changes to the original design certification are so extensive that the NRC concludes an essentially new standard design is being proposed, then the applicant must submit an application for a new design certification under § 52.45.

Under paragraph (d), denial by the NRC of a request for renewal of a design certification does not prevent an applicant from submitting a new application for certification under § 52.45.

§ 52.61 Duration of renewal.

This section specifies the duration that a renewed design certification is valid for referencing in a combined license application.

§ 52.63 Finality of standard design certifications.

The purpose of this section is to set forth the criteria for amending existing DCRs or issuing orders to nuclear plants that referenced a DCR. The amendment process places a designer on the same footing as the Commission or any other interested member of the public (see April 18, 1989; 54 FR 15377, first column). Therefore, it cannot be said that this section

makes it easier for a designer to amend certification information than for the NRC to backfit the certified design.

No matter who proposes it, a generic change will not be made to a DCR while it is in effect unless the change: (1) is necessary for compliance with Commission regulations applicable and in effect at the time the certification was issued; (2) is necessary to provide adequate protection of the public health and safety or common defense and security; (3) reduces unnecessary regulatory burden and maintains protection to public health and safety and common defense and security; (4) provides the detailed design information necessary to resolve selected design acceptance criteria; (5) corrects errors in the certification information; or (6) contributes to increased standardization of the certification information.

The new rule adds four new provisions to the amendment process. Paragraph (a)(1)(iii) allows the Commission to change the DCRs to reduce unnecessary regulatory burdens, *i.e.*, incorporate the revised § 50.59 change criteria, or change the certification information if the change provides a reduction in regulatory burden and maintains protection to public health and safety and common defense and security. Maintaining protection generally embodies the same safety principles used by the NRC in applying risk-informed decision-making, *e.g.*, ensuring that adequate protection is provided, applicable regulations are met, sufficient safety margins are maintained, defense-in-depth is maintained, and that any changes in risk are small and consistent with the Commission's Safety Goal Policy Statement (refer to NRC's RG 1.174).

Paragraph (a)(1)(iv) allows for generic resolutions of DAC. By allowing a DCR amendment to generically resolve selected DAC, the Commission will achieve resolution of additional design issues, will achieve finality for those issue resolutions, and will avoid repetitive consideration of those design issues in individual combined license proceedings. Also, these amendments will enhance standardization by further completing the certification information.

The NRC staff will review the amendment application to ensure that the DAC are met and that the new design information conforms with the applicable regulations.

Paragraph (a)(1)(v) allows for generic resolutions of errors in the certification information. The Commission wants to correct any design errors made by the applicant and any NRC review errors, then resolve them generically so that these errors will not have to be addressed in individual licensing proceedings. If the NRC receives a petition to amend a DCR, it will use this review opportunity to ensure that the certification information is in conformance with applicable regulations and correct any errors that are identified by the petitioner or discovered by the NRC staff.

Finally, paragraph (a)(1)(vi) allows for amendments that would increase standardization of the certification information. The Commission is still committed to achieving and maintaining the benefits of standardization. Therefore, it decided to allow amendments for changes other than those identified above provided that the amendment is applied to all plants that reference the DCR. In determining whether to codify a proposed amendment, the Commission will give special consideration to comments from applicants or licensees who referenced the DCR regarding whether they want to backfit their plants with these additional design changes.

Generic changes (amendments) to DCRs must be accomplished through rulemaking, with opportunity for public comment under paragraph (a)(2). For those DCRs that use the two-tiered rule structure, generic changes to both Tier 1 and Tier 2 information will be requested under paragraph (a)(1). Once a DCR is changed through rulemaking, under paragraph (a)(3) the changes will apply to all future applications referencing the DCR as well as all current plants referencing the design certification, unless the change has been rendered “technically irrelevant” through other action taken under paragraphs (a)(4) or (b)(1) of this section. Thus, standardization is maintained by ensuring that any amendment to a DCR is imposed upon all

nuclear power plants referencing the design certification rule. The duration of the amended DCR will be the same time period as the original DCR.

Paragraph (a)(4) sets forth the criteria that must be met before the Commission can impose new requirements by plant-specific order on a nuclear plant that references a design certification rule. Under this paragraph, the Commission must meet either the compliance or adequate protection backfit criteria and cite one or more special circumstances as defined in 10 CFR 50.12(a)(2). In addition, the Commission shall consider whether the special circumstances that justify the plant-specific order outweigh any decrease in safety that may result from the reduction in standardization cause by the plant-specific order. This additional requirement was added to ensure that the benefits of standardization will be preserved.

Paragraph (a)(5) sets forth the finality of matters that are resolved as part of a design certification rulemaking. Each of the DCRs have detailed provisions on the issues that were resolved for that standard plant design and detailed processes for changes to and departures from certification information (refer to Sections VI and VIII of appendices A, B, C, or D to part 52), which reference § 52.63.

Paragraphs (b)(1) and (b)(2) provide processes for requesting exemptions and departures from certification information. As part of its adoption of a two-tiered rule structure (refer to SRM on SECY-90-377, dated February 15, 1991), the Commission codified detailed processes for changes to and departures from certification information in each of the design certification rules (refer to Section VIII of appendices A, B, C, or D to part 52). The processes for a specific certified design must be used when requesting exemptions and departures from certification information.

Paragraph (c) identifies the detailed design information that an applicant for a combined license must have completed and available for audit by the NRC. The NRC expects that design certification applicants (vendors) will have this information available during the review of a

combined license application that references the certified design. Because a rule certifying a standard plant design does not belong to the designer (vendor), an applicant for a combined license that references the DCR could use a vendor other than the applicant that achieved the design certification. In that situation, the combined license applicant must acquire the detailed design information identified in paragraph (c) in order to demonstrate that the new vendor has the ability to provide the certified design and that the combined license applicant's design information is consistent with the design information in the DCR.

Subpart C - Combined Licenses

§ 52.71 Scope of subpart.

This section describes the scope of the requirements in this subpart. Under this subpart an applicant can request a combined construction permit and operating license with conditions (combined license) for a nuclear power facility. The combined license is essentially a combination of a construction permit, which requires consideration and resolution of many of the issues currently considered at the operating license stage, and a conditional operating license. Operation is allowed only after the Commission has made the finding that all acceptance criteria in ITAAC have been met.

The combined license application could describe a site and a custom design, or it could reference an early site permit (subpart A of part 52), a standard design certification (subpart B of part 52), a standard design approval (subpart E of part 52), or a reactor manufactured under a manufacturing license (subpart F of part 52) or a combination thereof. Although a pre-approved site and certified standard design need not be referenced for the combined license,

maximum efficiency will result if site-related issues, as well as design-related issues, have been resolved before commencement of the combined license proceeding.

§ 52.73 Relationship to other subparts.

The purpose of this section is to explain the relationship of the combined license process to the licensing processes in subparts A, B, E, and F of 10 CFR part 52.

§ 52.75 Filing of applications.

This section explains who can file, how to file, and the fees for NRC review of an application for a combined license.

§ 52.77 Contents of applications; general information.

This section sets forth the type of general information that is required to be included in an combined license application, namely, the information required by 10 CFR 50.33. Section 50.33 requires that the application include information such as the name and address of the applicant, a description of the business or occupation of the applicant, citizenship information of the applicant, the class of license applied for, the use to which the facility will be put, the time for which the license is sought, financial qualification information, State and local emergency response plans, the earliest and latest dates for the completion of construction, and information about decommissioning funding. Section 50.33 also provides requirements for the handling of Restricted Data or other defense information in an application.

§ 52.79 Contents of applications; technical information in final safety analysis report.

The purpose of this section is to identify specific technical information to be included in the final safety analysis report as part of an application for a combined license. This generally includes the same information required of applicants for construction permits and operating licenses under 10 CFR part 50. It also includes requirements for descriptions of operational programs that need to be included in the FSAR to allow a reasonable assurance finding of acceptability. These additional requirements are in support of the Commission's direction to the staff in SRM-SECY-02-0067 dated September 11, 2002, "Inspections, Tests, Analyses, and Acceptance Criteria for Operational Programs (Programmatic ITAAC)," that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application. In this SRM, the Commission stated:

[a]n ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage. The burden is on the applicant to provide the necessary and sufficient programmatic information for approval of the COL without ITAAC.

The Commission clarified its definition of *fully described* in SRM-SECY-04-0032, "Programmatic Information Needed for Approval of a Combined License Application Without Inspections, Tests, Analyses, and Acceptance Criteria," dated May 14, 2004, as follows:

In this context, *fully described* should be understood to mean that the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability. Required programs should always be described at a functional level and at an increased level of detail

where implementation choices could materially and negatively affect the program effectiveness and acceptability.

Accordingly, this section contains requirements for descriptions of operational programs and their implementation.

Paragraph (b) describes the information that is needed if the application references an early site permit. Although a combined license applicant referencing a certified design need not resubmit information or analyses submitted in connection with the early site permit, the combined license application FSARs must either include or incorporate by reference the SSAR for the early site permit. The SSAR must be included or incorporated into the combined license FSAR to ensure that matters addressed in the SSAR legally become part of the FSAR upon issuance of the combined license. This will also ensure that the information in the SSAR is subject to control under § 50.59 after issuance of the combined license. This provision is meant to convey that the combined license applicant referencing the early site permit does not need to resubmit, for NRC review, information or analyses that were already reviewed and resolved in the early site permit proceeding (such as information provided in responses to NRC requests for additional information). At the same time, this provision provides combined license applicants guidance as to what the combined license application must contain to be considered complete, including a requirement that it contain or incorporate the early site permit SSAR.

Because an early site permit applicant need not specify a particular nuclear plant design, the combined license application must demonstrate that the design of the facility falls within the site characteristics and postulated design parameters evaluated in the NRC's review and specified in the early site permit. If the application does not demonstrate that design of the facility falls within the site characteristics and design parameters of the early site permit, then, the applicant must request for a variance from the early site permit. Paragraph (b) requires that the application demonstrate that all terms and conditions in the early site permit, excluding

terms and conditions imposed under § 50.36b, be satisfied by the date of issuance of the combined license. Any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license must be set forth as terms or conditions of the combined license. Early site permit conditions imposed under § 50.36b are to be addressed in the environmental report and not in the FSAR.

Paragraph (b) also addresses emergency planning information submitted in a referenced early site permit and requires that the combined license application include any new or additional information to update or correct information provided with the early site permit and to discuss whether the new information may materially change the bases for compliance with the applicable NRC requirements. New information which materially changes the bases for compliance includes: (1) information which substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, as well as (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness in accordance with § 52.39(a)(1). New information that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for Commission to modify or impose new terms and conditions related to emergency preparedness would be subject to litigation during the combined license proceeding in accordance with § 52.39(c). This paragraph also addresses referenced early site permit emergency plans that incorporate existing emergency plans and requires the combined license application to identify changes to the emergency plans that constitute a decrease in effectiveness under 10 CFR 50.54(q). This requirement ensures that the NRC can review such changes to assess their impact on the emergency plans for the proposed combined license facility.

Paragraph (c) and (d) provide application requirements for a combined license that is referencing a standard design approval or a standard design certification, respectively. Similar

to a combined license application referencing an early site permit, a combined license application referencing a design approval or design certification must either include or incorporate by reference the design approval or design certification FSAR. Because a design approval or design certification applicant need not specify a particular site, the combined license application must demonstrate that characteristics of the site fall within the site parameters specified in the design approval or design certification. In addition, the plant-specific PRA information must use the PRA information for the design certification and must be updated to account for site-specific design information and any design changes or departures. An applicant referencing a design certification must demonstrate that the interface requirements established for the design have been met. Applicants referencing either a design approval or a design certification must demonstrate that any terms and conditions in the design approval or requirements and restrictions in the referenced design certification rule will be satisfied by the date that the combined license is issued. Any terms or conditions of the design approval that cannot be met or satisfied by the time of issuance of the combined license must be set forth as terms or conditions of the combined license. Likewise, any requirements or restrictions of the design certification that cannot be met or satisfied by the time of issuance of the combined license must be set forth as terms or conditions of the combined license.

Paragraph (e) describes the information that is needed if the combined license application references one or more manufactured reactors. Similar to a combined license application referencing an early site permit, design approval, or design certification, a combined license application referencing one or more manufactured nuclear power reactors under subpart F or part 52 must either include or incorporate by reference the manufacturing license FSAR. Because a manufacturing license applicant need not specify a particular site for the installation of a manufactured reactor, the combined license application must demonstrate that the site parameters for the manufactured reactor are bounded by the site where the

manufactured reactor is to be installed and used. In addition, the plant-specific PRA information must use the PRA information for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures. The combined license application must also demonstrate that the interface requirements established for the design have been met and that any terms and conditions in the manufacturing license will be satisfied by the date that the combined license is issued. Any terms or conditions of the manufacturing license that could not be met by the time of issuance of the combined license must be set forth as terms or conditions of the combined license.

§ 52.80 Contents of applications; additional technical information.

This section covers the required technical contents of a combined license application that are not contained in the FSAR. These application contents include the proposed ITAAC, the environmental report, and information to address an applicant's request to perform activities at the site allowed by 10 CFR 50.10(e) before issuance of the combined license.

Paragraph (a) requires the application to include the proposed ITAAC and, if the application references an early site permit with ITAAC or a design certification, requires the applicant to use the ITAAC contained in the early site permit or design certification for the applicable portion of the combined license application. ITAAC that must be included are those that are necessary and sufficient to demonstrate that the facility has been constructed and will operate in conformity with the combined license, the Atomic Energy Act of 1954 and the Commission's regulations. In addition, under Section 52.103(g), the Commission must find that all acceptance criteria specified in the license are met before facility operation. Because ITAAC are the sole source of acceptance criteria for subsequent resolution of items which cannot be

fully evaluated prior to issuance of a combined license, it is essential that the combined license ITAAC include all significant issues that require satisfactory resolution before fuel loading.

This paragraph also provides an applicant for a combined license with a process for resolving certain acceptance criteria in one or more of the ITAAC before issuance of the combined license. This provision is included mainly to allow for completion of DAC at the combined license application stage because applicants might want to complete certain DAC before construction. DAC are special design certification rule ITAAC. DAC set forth processes and criteria for completing certain design information, such as information about the digital instrumentation and control system. Many DAC were originally written to be verified as part of the normal, post-combined license, ITAAC verification process. Completion of the design matters covered by DAC before the issuance of a combined license is consistent with the Commission's original concept for design certification and issuance of a combined license. When it adopted 10 CFR part 52, the Commission intended that a design certification contain final and complete design information. Allowing a finding of acceptable completion of DAC before issuance of a combined license is, therefore, consistent with the Commission's original intent. Second, completion of DAC before issuance of the combined license is consistent with the Commission's goal of resolving issues before construction. Determining whether DAC have been successfully completed before issuance of the combined license avoids the possibility that improperly completed DAC will result in the construction of improperly designed structures, systems, and components. Accordingly, a finding of successful completion of DAC may be made when a combined license is issued, if the combined license applicant demonstrates that the DAC have been successfully completed. This process would also allow findings on successful completion of inspections or tests of components procured before the issuance of the combined license.

Paragraph (b) requires a complete environmental report in accordance with 10 CFR 51.50(c).

Paragraph (c) requires that, if the applicant is requesting to perform any activities at the site allowed by 10 CFR 50.10(e), then the applicant must identify and describe the activities and propose a plan for redress of the site in the event that the activities are performed and either construction is abandoned or the combined license is revoked. This paragraph also requires the applicant to demonstrate that there is reasonable assurance that redress carried out under the plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws. These requirements attempt to limit, to the extent practicable, the environmental impact of any site work done in the case where construction of the nuclear power facility is not completed.

§ 52.81 Standards for review of applications.

This section identifies the regulations that the NRC staff will use in performing its review of an application for a combined license.

§ 52.83 Finality of referenced NRC approvals; partial initial decision of site suitability.

This section describes the finality of regulatory products that may be referenced in a combined license application. Specifically, paragraph (a) states that the finality of matters resolved in a referenced early site permit, design certification, design approval, or manufacturing license are governed by the finality provisions in the respective subparts that address each of these regulatory processes. Paragraph (b) states that, while a partial decision

on site suitability is in effect under 10 CFR 2.617(b)(2), the finality provisions in 10 CFR 2.629 govern the scope and nature of matters resolved in the proceeding.

§ 52.85 Administrative review of applications; hearings.

This section identifies the procedural requirements that apply to the mandatory combined license hearing. This section also identifies that, if an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing.

§ 52.87 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

This section states that the ACRS will report on those portions of the application which concern safety.

§ 52.91 Authorization to conduct site activities.

The purpose of this section is to outline the activities that can be performed at the site by a combined license applicant. Paragraph (a) of this section discusses the authorization a combined license applicant needs to obtain in order to perform limited work activities at the site while the NRC is considering the combined license application in the case where a combined license applicant does not reference an early site permit that contains a redress plan. The requirements contained in paragraph (a) discuss work commonly referred to as a limited work authorization 1 (LWA-1) that is allowed in accordance with the requirements contained in

10 CFR 50.10(e)(1). These requirements do not allow the applicant to perform LWA-1 activities without first submitting a redress plan and obtaining the separate authorization required by 10 CFR 50.10(e)(1). Plans are expected to be modeled on the Midland Site Stabilization Report that was submitted on October 2, 1986 (ADAMS Accession #8610200370, Docket Nos. 50-329 & 50-330).

Paragraph (a) recognizes this possibility and notes that authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by 10 CFR 50.10(e)(2) and has determined that redress carried out under the site redress plan will return the site to an aesthetically acceptable and environmentally stable condition.

Paragraph (b) contains requirements for work commonly referred to as an LWA-2. An LWA-2 allows structural work for structures, systems, and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Because the design must be known to obtain authorization for LWA-2 activities, an LWA-2 is an option for a combined license applicant but not an option for an early site permit holder. A combined license applicant may request LWA-2 authority prior to the combined license being granted. Paragraph (b) recognizes this possibility and notes that authorization may be granted only after the presiding officer in the combined license makes the additional finding required by 10 CFR 50.10(e)(3)(ii), namely, that there are no unresolved safety issues relating to the LWA-2 activities.

Paragraph (c) of this section clarifies that, if work is performed either under an LWA-1, or LWA-2 or both, and the combined license application is subsequently withdrawn by the applicant or denied by the NRC, then the combined license applicant must redress the site in accordance with the terms of the site redress plan. Paragraph (c) of this section also provides

the combined license applicant with the ability to redress the site for an alternate use that was not considered at the time that the original redress plan was prepared.

§ 52.93 Exemptions and variances.

The purpose of this section is to describe the process for combined license applicants to obtain exemptions and variances. If the request is for an exemption from any part of a referenced design certification rule, the Commission can grant the request only if it determines that the exemption complies with any exemption provisions in the referenced design certification rule, or with § 52.63 if there are no applicable exemption provisions in the referenced design certification rule. A request for an exemption that is outside the scope of a design certification rule must be processed in accordance with the requirements contained in § 52.7.

For the General Electric ABWR, Westinghouse System 80+, Westinghouse AP600, and Westinghouse AP1000 designs, these requirements are contained in Section VIII, "Processes for Changes and Departures," of appendices A, B, C, and D respectively, of 10 CFR part 52. Section VIII of these appendices discusses the process for exemptions from different portions of the design certification rule. The section-by-section analysis for these respective rules discuss requirements regarding processing of exemptions that are expected to be carried forward to future design certification rulemakings. Therefore, if applicable, the applicant should refer to the respective section-by-section analysis in the portion of the design certification rule that discusses exemptions for additional information. Exemptions requested in accordance with this section are subject to litigation in the same manner as other issues in the licensee hearing.

Paragraph (b) of this section sets forth the process for requesting variances from an early site permit if one is referenced in the combined license. Paragraph (c) sets forth the process for requesting variances from one or more design characteristics, site parameters,

terms and conditions, or approved design of a manufactured reactor. Issuance of a variance is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

§ 52.97 Issuance of combined licenses.

The purpose of this section is to set forth the process for issuing a combined license. Paragraph (a)(1) of this section sets forth the requirements relative to the Commission findings that must be made for granting of a combined license.

Paragraph (a)(2) of this section allows for completion of certain acceptance criteria in one or more of the ITAAC in a combined license being met prior to granting of the combined license. This paragraph could apply to DAC found in the applicable design certification rules. DAC set forth processes and criteria for completing certain design information, such as information about the digital instrumentation and control system. Paragraph (a)(2) would allow the Commission to make a finding of successful completion of DAC when a combined license is issued, if the combined license applicant demonstrates that the DAC have been successfully completed. This process would also allow findings on successful completion of inspections or tests of components procured before the issuance of a combined license. Paragraph (a)(2) notes that such a finding will preclude any required finding under § 52.103(g) with respect to that ITAAC.

Paragraph (b) requires the Commission to identify the ITAAC within the combined license that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations. This definition of what ITAAC are intended to accomplish is consistent with

that contained in § 52.17 regarding early site permits, § 52.47 regarding design certifications and § 52.80, which are discussed above. If the combined license application references an early site permit with ITAAC related to emergency planning information, then the applicant must use these ITAAC in the emergency planning information submitted with the combined license application. If a combined license applicant references a design certification rule, the ITAAC contained in the license would be those contained in the design certification rule plus any additional ITAAC that were identified during the combined license review that were outside the scope of the certified design. If the Commission wishes to identify additional ITAAC that fall within the scope of the review of the referenced certified design it needs to meet the requirements contained in the design certification rule itself (see Section VIII.A.3 of appendix A, B, C, and D for the ABWR, System 80+, AP600, and AP1000) and the requirements contained in § 52.63. If a combined license applicant does not reference an early site permit or a certified design, then the ITAAC that are identified by the Commission for paragraph (b) of this section are those that were identified during the combined license review.

§ 52.98 Finality of combined licenses; information requests.

This section covers the finality of combined license provisions and sets forth the requirements to modify the combined license after it has been issued. After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the backfit provisions of §§ 52.103 or 50.109, as applicable.

Paragraphs (b), (c), and (d) outline the applicability of the change processes in 10 CFR part 50, Section VIII of the design certification rules, and subpart F of 10 CFR part 52 to a combined license. The change processes in 10 CFR part 50 apply to a combined license that does not reference a design certification rule or a reactor manufactured under a manufacturing license. Section 52.98(c) states that the change processes in Section VIII of the design certification rules apply to changes within the scope of the referenced certified design. However, if the proposed change affects the design information that is outside of the scope of the design certification rule, the part 50 change processes apply unless the change also affects the design certification information. For that situation, both change processes may apply. If the combined license references a reactor manufactured under a subpart F manufacturing license, then changes to or variances from information within the scope of the manufactured reactor's design are subject to the change processes in § 52.171.

Paragraph (e) was added in 1992, and discussed in the section-by-section analysis (57 FR 60976; December 23, 1992), as following:

This section has been amended with regard to making amendments to a combined license immediately effective under the so-called "Sholly Amendment." Under the Energy Policy Act, an amendment to a combined license can be made immediately effective if the Commission determines there are no significant hazards considerations. This section of the rule has been revised to incorporate the statutory provisions and previously issued Commission regulations implementing the "Sholly" amendment. The Commission, however, stresses that it will not look with favor upon license amendments to a combined license filed shortly before planned operation that could have the effect of undermining standardization or changing the scope of imminent or pending hearings on conformance issues.

Paragraph (f) states that any modification to a combined license is an amendment to the license and that there must be an opportunity for hearing on these amendments. Such amendments would be processed in accordance with the requirements contained in 10 CFR 50.90 and 50.91. In addition, if the applicant has referenced a certified design, or a reactor manufactured under a manufacturing license, additional requirements may apply. For example, a combined license that references an ABWR certified design may request an exemption from Tier 1 material in accordance with the provisions contained in Section VIII.A.4 of appendix A of 10 CFR part 52. In such a case, the licensee would have to process an exemption in accordance with the requirements contained in appendix A to part 52 and 10 CFR 52.63(b)(1) and a license amendment in accordance with paragraph (f) of this section.

Paragraph (g) which is analogous to §§ 52.39(f), 52.145(c), and 52.171(c), provides that NRC information requests must be evaluated before issuance to ensure that the burden to imposed by the information request is justified in view of the potential safety significance of the issue to be addressed, except when the information requests seeks to verify compliance with the current licensing basis of the combined license. Information requests may be in the form of a new rule requiring submission of information (*i.e.*, a new information collection and reporting requirement), or in the form of a NRC staff request for information. Information requests by the staff must be in accordance with 10 CFR 50.54(f) and must be approved by the EDO or his or her designee before the request may be issued.

§ 52.99 Inspection during construction.

The purpose of this section is to set forth the requirements to support the NRC's inspections during construction. A new § 52.99(a) has been added to require that the licensee submit to the NRC, no later than 1 year after issuance of the combined license, its detailed

schedule for completing the inspections, tests, or analyses in the ITAAC. This provision also requires the licensee to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee must submit updates to the ITAAC schedule every 30 days. The information provided by the licensee will be used by NRC in developing the NRC's inspection activities and activities necessary to support the Commission's finding whether all of the ITAAC have been met prior to the licensee's scheduled date for fuel load. Even in the case where there were no changes to a licensee's ITAAC schedule during an update cycle, the NRC expect the licensee to notify the NRC that there have been no changes to the schedule.

Section 52.99 has also been amended to incorporate rule language from the design certification rules in 10 CFR part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of appendix A to part 52). During the preparation of the design certification rules for the ABWR and System 80+ designs, the NRC staff and nuclear industry representatives agreed on certain requirements for the performance and completion of the inspections, tests, or analyses in ITAAC. In the design certification rulemakings, the Commission codified these ITAAC requirements into Section IX of the regulations. The purpose of the requirement in § 52.99(b) is to clarify that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been met.

Section 52.99(c)(1) requires the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met. Section 52.99(c)(1) further requires that the notification contain sufficient information to demonstrate that the acceptance criteria for the ITAAC have been met.

Section 52.99(c)(2) requires that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by § 52.99(c)(1) for all ITAAC, then the licensee must notify the NRC that the inspections, tests, or analyses for all uncompleted ITAAC will be successfully completed and all acceptance criteria will be met prior to initial operation (consistent with the Section 185.b requirement that the Commission, “prior to operation,” find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the inspections, tests, or analyses will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met.

Section 52.99(c) ensures that: (1) the NRC has sufficient information to complete all of the activities necessary for the Commission to make a determination as to whether all of the ITAAC have been or will be met prior to initial operation; and (2) interested persons will have access to information on both completed and uncompleted ITAAC at a level of detail sufficient to meet the AEA Section 189.a(1)(B) threshold for requesting a hearing on acceptance criteria. Thus, the NRC expects that the information submitted under paragraph (c)(1) to be more than a simple statement that the licensee believes the ITAAC has been completed and the acceptance criteria met. Furthermore, the NRC expects that the information that the licensee submits under paragraph (c)(2) with respect to uncompleted ITAAC to be sufficiently detailed such that the NRC can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. In sum, the information submitted by licensees under both § 52.99(c)(1) and (c)(2) notifications must be

sufficiently complete and detailed such that any licensee response to a contention on uncompleted ITAAC would ordinarily be answered solely by reference to information contained in the notification, and that the level of detail provided by the licensee should be sufficient to allow a prospective intervener to form such judgments by reference to that information.

The NRC notes that, even though it did not include a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date, the NRC staff will require some period of time to perform its review of the last ITAAC once the licensee submits its notification that the ITAAC has been successfully completed and the acceptance criteria met. In addition, the Commission itself will require some period of time to perform its review of the staff's conclusions regarding all of the ITAAC and the staff's recommendations regarding the Commission finding under § 52.103(g). Therefore, licensees should structure their construction schedules to take into account these time periods.

A new paragraph (d) states the options that a licensee will have in the event that it is determined that any of the acceptance criteria in the ITAAC have not been met. If an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under § 52.98(f). Also, if an activity that is subject to an ITAAC is not derived from a referenced standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under § 52.98(f).

Paragraph (e)(1) of this section indicates that the NRC is responsible for ensuring (through its inspection and audit activities) that the combined license holder performs and documents the completion of inspections, tests, and analyses in the ITAAC. When part 52 was

first adopted by the Commission in 1989 (April 18, 1989; 54 FR 15372), the rule provided that the NRC staff shall ensure that the inspections, tests, and analyses in the ITAAC are performed, and did not refer to the Commission finding on acceptance criteria being met. The Commission revised the language in this portion of the rule in 1992 (December 23, 1992; 57 FR 60975) to reflect changes to Section 185 of the AEA made by Congress in the Energy Policy Act of 1992 (1992 EPA), which states:

Following issuance of the combined license, the Commission shall ensure that the prescribed inspections, tests, and analyses are performed and, prior to operation of the facility, shall find that the prescribed acceptance criteria are met.

Thus, the revisions to this portion of the rule in 1992 simply reflected the language of the 1992 EPA. However, the Commission does not believe that Congress, by adopting language in Section 185 stating that the Commission shall ensure that the ITAAC are performed, intended to prohibit the Commission's long-standing practice of delegating to the NRC staff the responsibility for performing the necessary activities, including audits and inspections, to ensure that "the required inspections, tests, and analyses in the ITAAC are performed." Accordingly, the language from the 1992 rule change is retained in this final rule.

Paragraph (e)(1) requires the NRC to publish, at appropriate intervals until the last date for submission of requests for hearing under § 52.103(a), notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

Paragraph (e)(2) provides that the NRC shall make publicly available the licensee notifications under paragraphs (c)(1) and (c)(2). In general, the NRC expects to make the paragraph (c)(1) notifications availability shortly after the NRC has received the notifications and concluded that they are complete and detailed. Furthermore, by the date of the *Federal Register* notice of intended operation and opportunity to request a hearing on whether acceptance criteria have been or will be met (under § 52.103(a)), the NRC will make available the notifications under

paragraph (c)(2), and the notifications under paragraph (c)(2) for all ITAAC for which paragraph (c)(1) notifications have not been provided by the licensee.

§ 52.103 Operation under a combined license.

The purpose of this section is to set forth the requirements for operation under a combined license. This section has been previously discussed in a section-by-section analysis for the 1992 revisions to part 52 (57 FR 60976; December 23, 1992) which the NRC adopted in response to the Energy Policy Act of 1992. The 1992 section-by-section analysis states:

In an effort to adhere as closely as possible to the new statutory requirements of the Energy Policy Act, the NRC has replaced most of its old § 52.103 with the text of section 2802 of that Act. Under the revised language, any request for a post-construction hearing must show, prima facie, both that one or more of the acceptance criteria are not or will not be met, and those specific operational consequences of nonconformance that would be contrary to providing reasonable assurance that the public health and safety will be adequately protected. The Commission may permit interim operation of a facility pending a hearing if it determines that this assurance exists. The Commission has the discretion to decide if any post-construction hearing will use formal or informal hearing procedures, and it must state publicly the reasons for choosing either set of procedures. The Commission must find, prior to operation of the facility, that the acceptance criteria have been met.

Paragraph (a) of this section is revised to require licensees to notify the NRC of its schedule date for initial loading of fuel no later than 270 days before the scheduled date and to notify the NRC of updates to its schedule every 30 days thereafter. This information will be

used by the NRC to develop the notice of intended operation in the *Federal Register*, which must be published not less than 180 days before the licensee's initial fuel load date, as required by Section 189.a.(1)(B) of the AEA. In addition, paragraph (a) addresses the possibility that an applicant for a combined license may choose to resolve certain acceptance criteria in one or more of the ITAAC required by § 52.80 before issuance of the combined license. In such a case, if the Commission makes a finding in accordance with § 52.97 associated with these ITAAC at the time that a combined license is granted, these ITAAC would not be subjected to a hearing opportunity again under paragraph (a) of this section. The section-by-section analysis for § 52.97 discusses this issue in more detail.

Paragraph (b) provides the criteria that must be met for any request for a hearing on whether the facility complies or will comply with the acceptance criteria. The petitioner must set forth with reasonable specificity the facts and arguments which form the basis for the request. These provisions are designed to accord finality to the Commission's earlier decisions regarding the facility and to ensure that any proceeding is focused on significant safety issues.

Paragraph (c) requires the Commission to expeditiously either deny or grant any request for a hearing under this section. If a request is granted, the Commission must determine whether to allow interim operation of the facility based on reasonable assurance of adequate protection of the public health and safety.

Paragraph (d) provides that the Commission will determine the appropriate hearing procedures in accordance with 10 CFR part 2 for any hearing under paragraph (a) of this section. Under § 2.309, as adopted by the Commission in 2004 (69 FR 2182; January 14, 2004), such a hearing would ordinarily be conducted under subpart L of part 2. However, the Commission may direct, in the notice of required by paragraph (a) or in a subsequent order, that any hearing that may be conducted in a particular combined license proceeding under paragraph (a) use other, less formal hearing procedures, consistent with the requirements of

the AEA. Any such Commission direction is consistent with the Commission's statement in the SOC for the 1989 final part 52 rulemaking (54 FR 15372, 15383; April 18, 1989) that any hearing held under former § 52.103(b)(2)(i) (§ 52.103(b) in this final rule) will use informal procedures to the maximum extent practical and permissible under law.

Paragraph (e) states that the Commission will, to the maximum extent possible, render a decision on issues raised in any hearing request within 180 days of the publication of the notice or by the anticipated date for initial fuel load, whichever is later.

Paragraph (f) provides requirements related to the submittal of petitions to modify the terms and conditions of a combined license and states that fuel loading and operation under a combined license will not be affected by the granting of a petition unless the Commission makes an order immediately effective.

Paragraph (g) prohibits the licensee from operating the facility until the Commission makes a finding that the acceptance criteria in the combined license are met (except for acceptance criteria that the Commission found were met when the combined license was issued). The NRC believes that the rule should reflect, as closely as possible, the statutory requirement in Section 185.b of the AEA. Although the NRC has historically viewed "operation" as including loading of fuel into the reactor, the NRC believes it is not necessary to change the language of § 52.103(g) to continue the historical practice.

Paragraph (h) of this section incorporates rule language from the design certification rules in 10 CFR part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of appendix A to part 52). This paragraph states that ITAAC do not, by virtue of their inclusion in the design certification rule or combined license, constitute regulatory requirements after the licensee has received authorization to load fuel or for any renewal of the license. However, subsequent modifications to the facility or procedures described in the FSAR must comply with the requirements in § 52.98.

§ 52.104 Duration of combined license.

This section addresses the duration of a combined license which is a period not to exceed 40 years from the date that the Commission makes the finding that the acceptance criteria in the license are met, in accordance with § 52.103(g). Where the Commission has allowed operation during an interim period under § 52.103(c), the period of operation is not to exceed 40 years from the date allowing operation during the interim period. This provision implements Section 621 of the Energy Policy Act of 2005 which amended Section 103c. of the AEA. The AEA provided that the 40 year duration started on the date that the Commission authorized construction of the facility (*i.e.*, the date of issuance of the combined license).

§ 52.105 Transfer of combined license.

This section states that a combined license may be transferred in accordance with 10 CFR 50.80, "Transfer of licenses." Section 50.80 provides the requirements regarding application for a license transfer. All license transfers must be approved by the Commission.

§ 52.107 Application for renewal.

This section states that an application to renew a combined license must be in accordance with 10 CFR part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants."

§ 52.109 Continuation of combined license.

This section, which is analogous to § 50.51, provides requirements for a combined license facility that has permanently ceased operations and states that the license continues in effect beyond the expiration date until the Commission notifies the licensee in writing that the license is terminated. During this period, the licensee is required to decommission and decontaminate the facility; maintain the facility, including the spent fuel, in a safe condition; and continue to follow the NRC's regulations and the provisions of the combined license.

§ 52.110 Termination of license.

This section, which is analogous to § 50.82, provides requirements the termination of a combined license. These provisions include a requirement to notify the NRC within 30 days when a licensee has decided to permanently cease operations and to submit a certification to the NRC once fuel has been permanently removed from the reactor vessel. This section also requires decommissioning of the facility within 60 years of permanent cessation of operations and outlines requirements regarding decommissioning activities.

Subpart E - Standard Design Approvals

§ 52.131 Scope of subpart.

This section describes the scope of this process for design approvals of standard nuclear power plants or major portions thereof, *i.e.*, a nuclear steam supply system or balance of plant. Under this subpart an applicant may request pre-approval of a standard nuclear power plant design, separate from a site review or other licensing action, and subsequently have that

design approval referenced in an application to build a nuclear power plant. This licensing process was first adopted by the Commission in 1975 and has been used many times.

§ 52.133 Relationship to other subparts.

The purpose of this section is to explain the relationship of the standard design approval process to the processes set forth in subparts B, C, and F of 10 CFR part 52, which provide for design certifications, combined licenses, and manufacturing licenses. The Commission continues to believe that the best approach for obtaining early resolution of design issues is through the design certification process in subpart B of this part. Applicants for a design approval have the option of also applying for design certification. Applicants for a combined license or a manufacturing license may reference a design approval.

§ 52.135 Filing of applications.

This section explains how to file an application for a standard design approval and how the fees for NRC's review of the application will be assessed. Applications are limited to final design information, in order to remove the unpredictability of issuing a construction permit that references only preliminary design information and initiating construction while the final design information is being completed. Approval of a final standard design ensures early consideration and resolution of technical matters by the NRC staff before there is any substantial commitment of resources, which will greatly enhance regulatory stability and predictability.

§ 52.136 Contents of applications; general information.

This section identifies the general information that must be included in all applications.

§ 52.137 Contents of applications; technical information.

The purpose of this section is to identify the technical information that must be included in an application for a design approval. Paragraphs (a) and (c) describe information that must be included in the FSAR, which is included in the application, and paragraph (b) describes the information that must also be included in the application but does not need to be included in the FSAR. Applications for a major portion of the plant design, such as the nuclear steam supply system, only need to contain the technical information that is applicable to the major portion of the plant for which NRC staff approval is requested.

Many of the requirements in this section were taken from 10 CFR 50.34 or are pointers to technical requirements in parts 20, 50, and 73 that must be addressed in the application. The requirements taken from § 50.34 are a subset of the information required of applicants for construction permits and operating licenses. Other requirements came from appendix O to part 50 or were created by the Commission during its simultaneous reviews of applications for design approvals and design certifications.

Although an applicant for design approval does not need to specify a particular site for the nuclear power plant, which is required in a combined license application, it does need to identify the site parameters that the standard nuclear power plant or major portion thereof is designed to meet, *e.g.*, postulated values for the safe shutdown earthquake response spectra and maximum tornado wind speed. These parameters are usually selected to envelop a large portion of nuclear plant sites in the United States. Once the design is approved by the NRC, conformance of the actual site characteristics with the established site parameters must be

demonstrated by an applicant referencing the design approval and verified by the NRC staff at the time that the referencing application is submitted, *i.e.*, combined license application.

Paragraph (a)(7) requires the applicant for design approval to describe its qualifications to design and analyze a standard nuclear power plant.

In its staff requirements memorandum (SRM) on SECY-90-377, "Requirements for Design Certification under 10 CFR Part 52," dated February 15, 1991, the Commission stated that information submitted in an application should incorporate the experience from operating events in current designs which we want to prevent in the future. Paragraph (a)(22) requires the applicant to demonstrate how relevant operating experience insights have been incorporated into the design. Operating experience includes consideration of operating events and the reliability and performance of structures, systems, and components. Regarding the requirement to address comparable international operating experience, the NRC understands that some future applications may be for designs that are not based on or evolutions of plant designs that have operated in the United States. Those applications should address how insights from relevant international operating experience have been incorporated into the plant design.

In its SRMs, dated June 26, 1990, and July 21, 1993, on SECY-90-16, "Evolutionary Light-Water Reactor Certification Issues and their Relationship to Current Regulatory Requirements," and SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Designs," respectively, the Commission approved NRC staff recommendations for selected preventative and mitigative design features for future light-water reactor designs. Paragraph (a)(23) requires the applicant to provide a description and analysis of those design features discussed in SECY-90-16 and SECY-93-87.

Paragraph (a)(24) requires the application to describe the interfaces for those design features that are outside the scope of the approved design, *e.g.*, service water intake structure

or ultimate heat sink or, if the application is for approval of a major portion of the plant design, the interfaces between the nuclear steam supply system and the balance of plant.

Paragraph (a)(25) requires the applicant to provide a description of the design-specific PRA and its results. Guidance on meeting the PRA information requirements will be provided in separate regulatory guidance documents.

Paragraph (b) requires applications for “advanced” nuclear power plants to meet the design qualification testing requirements in 10 CFR 50.43(e). Advanced designs differ significantly from evolutionary light-water reactor designs or incorporate, to a greater extent than evolutionary designs do, simplified, inherent, passive, or other innovative means to accomplish their safety functions. Examples of advanced nuclear power plant designs include General Atomic’s Modular High Temperature Gas-Cooled Reactor, General Electric’s Simplified Boiling Water Reactor, and Westinghouse’s AP600.

§ 52.139 Standards for review of applications.

This section sets forth the parts of 10 CFR that contain applicable requirements for the technical review of applications for a design approval. The applicability of these requirements is specified in the identified parts. The Commission recognizes that new designs may incorporate design features that are not addressed by the current standards in 10 CFR parts 20, 50 and its appendices, 73, or 100 and that new standards may be required to address these new design features. The Commission will determine whether rulemakings are needed or appropriate to resolve generic safety issues that are applicable to multiple designs.

§ 52.141 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

This section states that the application for design approval shall be sent to the ACRS for its review of safety issues.

§ 52.143 Staff approval of design.

This section states that upon completion of the NRC staff's review of the standard design and receipt of a letter report from the ACRS, the staff shall issue a final safety evaluation report (FSER) and make that report available on the NRC's Web site. Also, if the FSER demonstrates that the standard design is acceptable, the Director of the Office of New Reactors or the Office of Nuclear Reactor Regulation may issue a final design approval with appropriate terms and conditions. The NRC's approval of a standard design is commonly referred to as an FDA because it is an approval of final design information.

§ 52.145 Finality of standard design approvals; information requests.

This section states that a valid FDA must be relied upon by the ACRS and NRR in any review of a license application that references the FDA unless significant new information substantially affects the staff's FSER. The Commission, Atomic Safety Licensing Board Panel, or presiding officers are not bound by NRC staff determinations in the FDA or FSER for the standard plant design. Therefore, there is no issue preclusion in the mandatory hearing for a combined license that references an FDA. Generic changes to the standard design can be made as a compliance backfit or under the backfit process in 10 CFR 50.109. Under paragraph (c), the justification for requests for information to FDA holders must be approved by the EDO or his or her designee, in accordance with the process set forth in 10 CFR 50.54(f).

§ 52.147 Duration of design approval.

The purpose of this section is to specify the time period that an FDA can be referenced in a construction permit, operating license, combined license, or manufacturing license application.

Subpart F—Manufacturing Licenses

§ 52.151 Scope of subpart.

This new section is analogous to the “scope of subpart” sections in subparts A through C of part 52 (*e.g.*, §§ 52.13, 52.41, 52.71). Section 52.151 describes the general subject matter of subpart F as the requirements and procedures applicable to NRC issuance of licenses authorizing the manufacture of nuclear power reactors to be installed at sites not identified in the manufacturing license application. This subpart does not cover the manufacture of subcomponents (*e.g.*, a pump or a reactor pressure vessel) or major subassemblies (*e.g.*, an integrated module consisting of a pump, piping and instrumentation and control) for installation in a nuclear power plant, either on a specific site, or being delivered for integration into a nuclear power plant under a manufacturing license issued under this subpart. For purposes of this subpart, a manufactured “nuclear power reactor” would not include site-specific SSCs such as the site foundation or SSCs related to the ultimate heat sink.

§ 52.153 Relationship to other subparts.

This new section is analogous to the “relationship to other subpart” sections in subparts A through C of part 52 (e.g., §§ 52.13, 52.43, 52.73). Section 52.153 explains how this subpart relates to other licensing processes in parts 50 and 52, as well as to the regulatory approvals in part 52.

A manufactured reactor may only be transported to and installed at a site for which either a construction permit under part 50 or a combined license under part 52 has been issued to a licensee, as stated in paragraph (a). However, the licensing requirements associated with transport of a manufactured reactor from its place of manufacture to the site where it is to be installed and operated are not addressed in this rulemaking.

The NRC will issue a manufacturing license only if it approves the final design of the reactor to be manufactured. Paragraph (b) provides that the manufacturing license applicant may reference either a standard design certification rule or a standard design approval, in order to speed the NRC’s review of the manufacturing license application. The language of paragraph (b) has been corrected in the final rule by deleting the reference to “preliminary or final” design approvals, inasmuch as the final part 52 rule no provides for preliminary design approvals.

§ 52.155 Filing of applications.

This new section is analogous to the “filing of applications” sections in subparts A through C of part 52 (e.g., §§ 52.15, 52.45, 52.75). Section 52.155 addresses who may file an application for a manufacturing license, the administrative requirements with respect to filing (referring to §§ 52.3 and 50.30), and the fees for filing and review of the application (referring to 10 CFR part 170). With respect to these matters, a manufacturing license application is no different than any other license application under parts 50 or 52, and the applicant shall comply

with all of these administrative requirements (which have been revised as part of the final rule to refer, as necessary, to manufacturing licenses).

§ 52.156 Contents of applications; general information.

This new section is analogous to the “contents of application; general information” sections in subparts A through C of part 52 (e.g., §§ 52.16, 52.46, 52.77). Section 52.156 requires that the applicant include the information set forth in § 50.33(a) through (d) and (j), which are the same information required to be supplied by applicants of construction permits, early site permits, operating licenses, and combined licenses. Paragraphs (a) through (d) of § 50.33 require an application to include information identifying the applicant, including its name, address, business or occupation, and certain corporate information, including whether it is owned, controlled, or dominated by an alien, foreign corporation, or foreign government. Paragraph (j) of § 50.33 require the applicant to segregate and protect any Restricted Data or other defense information from unclassified information. Manufacturing license applicants should note that there are other NRC requirements governing Restricted Data or National Security Information in other parts of 10 CFR Chapter 1, including 10 CFR parts 10, 50, and 95.

§ 52.157 Contents of applications; technical information in final safety analysis report.

This new section is analogous to the “contents of application; technical information” sections in subparts A through C of part 52 (e.g., §§ 52.17, 52.47, 52.79). Section 52.157 identifies the technical information that must be included in an application for a manufacturing license. These requirements were modeled on those subparts, in particular subpart B’s provisions dealing with standard design certifications, because of the commonality with respect

to the nature and scope of NRC approval of the design in both regulatory processes. As with the existing part 50 licensing process, and part 52's combined license and standard design certification processes, the manufacturing license application must include an FSAR. The FSAR contains the information necessary for the NRC to determine the safety of the reactor design to be manufactured and the adequacy of the applicant's proposed means of assuring that the manufacturing conforms to the design. The FSAR must contain a level of detail sufficient to permit preparation of construction and installation specifications by an applicant who seeks to use the manufactured reactor, and for the NRC to prepare acceptance and inspection requirements.

The information required to be included in the manufacturing license FSAR is largely the same as what is required for a design certification or combined license, but the requirements have been modified as necessary to reflect the fact that the design and manufacture of a reactor is being approved by license, but that the reactor must be transported to a site and integrated into site specific plant elements in order to operate. In addition, unlike the case with a design certification, the NRC is not distinguishing between evolutionary plants versus more advanced plants with respect to the level of detail required to be developed to support the license application. The NRC expects that the designs of all manufactured plants will be completed at a level of detail sufficient for: (1) the holder of the manufacturing license to develop procurement, construction and installation specifications; and (2) the NRC to develop acceptance and inspection requirements.

Paragraph (a) requires that the FSAR contain the principle design criteria for the reactor to be manufactured, and references appendix A to 10 CFR part 50 as establishing minimum requirements for the principle design criteria for water-cooled nuclear power plants. The NRC expects to develop technology-neutral design criteria for non-light water cooled reactor designs in the future. This requirement was drawn from § 50.34(a)(3)(i).

Paragraph (b) requires that the FSAR describe the design bases and the relation of the design bases to the principle design criteria that are identified in accordance with paragraph (a). This requirement was drawn from § 50.34(a)(3)(ii).

Paragraph (c) requires that the FSAR describe and analyze the structures, systems, and components of the reactor to be manufactured, with the objective of demonstrating that the necessary safety functions will be accomplished. This requirement was drawn from § 50.34(a)(1) and (b)(2), but modified to reflect the fact that a manufacturing license represents approval of a final reactor design.

Paragraph (d) requires that the FSAR describe the safety features that are engineered into the reactor. This requirement was drawn from § 50.34(a)(1)(ii)(D), but modified to reflect the fact that a manufacturing license represents approval of a final reactor design.

Paragraph (e) requires the FSAR to describe the kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20.

Paragraph (f) requires that the FSAR include that information necessary to establish that the design of the reactor to be manufactured complies with 18 delineated technical requirements in 10 CFR part 50. Applicants and licensees should note that the part 50 requirements listed in paragraph (f) do *not* constitute the sum total of requirements in part 50 for which either an applicant for or holder of a manufacturing license must comply with in its application and throughout the life of its license. Rather, the listed requirements in paragraph (f) simply represents *the minimum necessary content of the FSAR* for a manufacturing license. The part 50 requirements listed in paragraph (e) are mainly applicable to LWRs. Potential applicants and licensees should also note that the NRC may, in the future, adopt additional technical requirements in part 50 applicable to LWRs. If the NRC believes that future manufacturing license holder's compliance with that new requirement must be

documented and controlled through the FSAR, the NRC will make a conforming change in § 52.157 to refer to the new part 50 requirement. A similar course would also be followed if the NRC backfits, in accordance with the finality provisions in § 52.171, the new requirement on existing manufacturing licenses.

Paragraph (f)(19) requires that the FSAR include the site parameters postulated for the design of the manufactured reactor. Although an applicant for a manufacturing license does not need to specify a particular site where the manufactured reactor will be integrated into a nuclear power plant, as in a combined license application, it does need to identify the site parameters, under paragraph (f)(20), that the manufactured reactor is designed to meet, *e.g.*, postulated values for the safe-shutdown earthquake response spectra and maximum tornado wind speed. These parameters are usually selected to envelop a large portion of nuclear plant sites in the United States. Once the manufacturing license is issued by the NRC, conformance of the actual site with the established site parameters must be demonstrated by the applicant referencing the use of the manufactured reactor.

Paragraph (f)(20) requires the FSAR to describe the interface requirements for those design features that are outside the scope of the design of the manufactured reactor, *e.g.*, service water intake structure or ultimate heat sink, and paragraph (f)(21) requires justification that compliance with the interface requirements in paragraph (g) can be verified through inspections or tests (which may be conducted at the plant where the manufactured reactor is utilized, or elsewhere, *e.g.*, the place of manufacture) or analysis. This paragraph does not require, however, that the FSAR contain “acceptance criteria” for determining whether the interface requirements have been met.

Paragraph (f)(22) requires the FSAR to include a representative conceptual design for the nuclear power facility using the manufactured reactor. This will be used by the NRC in its review of the FSAR and the PRA required by § 52.158(a), to assess the adequacy of the

interface requirements in paragraph (g) of this section, and to help the Commission in determining the adequacy of the site parameters and design characteristics to be included in the manufacturing license. The conceptual design will not, however, be approved as part of the manufacturing license and the Commission does not anticipate directly requiring a nuclear power plant utilizing the manufactured reactor to use the conceptual design. Instead, the Commission intends to use site parameters, design characteristics, ITAAC, and interface requirements to ensure that the manufactured reactor will be utilized safely at a specific nuclear power plant.

Paragraph (f)(23) requires the applicant to provide a description and analysis of design features to address prevention and mitigation of severe accidents, consistent with the Commission's SRM on SECY-91-229, "Severe Accident Mitigation Design Alternatives for Certified Standard Designs," dated October 25, 1991.

Paragraph (f)(24) is reserved to accommodate any new requirement for the contents of an FSAR submitted as part of an application for a manufacturing license which the Commission may adopt in the future.

Paragraph (f)(25) requires FSARs for modular nuclear power plant designs to describe and analyze the various options for the configuration of the multi-reactor nuclear power plant. Modular nuclear power plant designs are defined in § 52.1. Modular designs are not portions of a single nuclear plant, rather they are separate nuclear reactors with some shared or common systems.

Paragraphs (f)(26)(i), (ii), (iii), and (v) focus on FSAR information necessary to demonstrate applicants technical, managerial, and organizational capability and resources to design and manufacture a nuclear power reactor consistent with the approved design, and in accordance with all applicable requirements.

Paragraph (f)(26)(iv) requires the FSAR to include proposed procedures for the preparation of the manufactured reactor for shipping, the conduct of shipping, and for verifying the condition of the manufactured reactor upon receipt at the site. However, the holder of the manufacturing license need not be responsible for implementing the procedures for verifying the condition of the reactor upon receipt at the site. The NRC will require the licensee whose application referenced the use of the manufactured reactor to implement the approved verification procedures (this could be done as a license condition). With respect to shipping, the holder of the manufacturing license may use an agent (e.g., a shipping company) to transport the reactor. To ensure that the shipping requirements in the manufacturing license are complied with by the third party transporter, the NRC has included a provision in § 52.167(c)(2) requiring the manufacturing license holder to include, in any contract governing the transport of a manufactured reactor from the place of manufacture to any other location, a provision requiring that the person or entity transporting the manufactured reactor to comply with all NRC-approved shipping requirements in the manufacturing license.

Paragraph (f)(29) requires the FSAR to include information describing how relevant operating experience insights from NRC's generic letters and bulletins, issued after the most recent revision of the applicable standard review plan, have been incorporated into the design of the reactor to be manufactured. Operating experience includes consideration of operating events and the reliability and performance of structures, systems, and components. Regarding the requirement to address comparable international operating experience, the NRC understands that some future applications may be for reactor designs that are not based on or evolutions of designs that have operated in the United States. Those applications should address how insights from relevant international operating experience have been incorporated into the reactor design.

Paragraph (f)(31) requires that the FSAR include a description of the design-specific probabilistic risk assessment and its results.

§ 52.158 Contents of application; additional technical information.

This new section is analogous, in organizational structure, to § 52.80, “Contents of application; additional technical information” in subpart C of part 52.

Paragraph (a) requires that the application include inspections, tests, and analyses that the licensee who will be placing the manufactured reactor on a site and operating the reactor shall perform and their associated acceptance criteria. The purpose of these ITAAC are to ensure that: (1) the reactor has been manufactured in conformance with applicable requirements; and (2) the manufactured reactor, as emplaced at the site and integrated into any site-specific portions of the nuclear power plant, will operate in conformance with the design characteristics in the manufacturing license, the license authorizing operation of the manufactured reactor, and applicable requirements. Paragraph (a)(3), which is analogous to § 52.80(b)(3), provides that if the manufacturing license references a standard design certification, the manufacturing license application may include a notification that one or more ITAAC in the referenced design certification rule has been met. In such a situation, the *Federal Register* notice of docketing a hearing required by § 52.163 must specifically indicate that the application includes such a notification.

Paragraph (b)(1) requires that the application include an environmental report meeting the requirements in 10 CFR 51.54, which specifies the environmental information that must be submitted by a manufacturing license applicant to support the NRC’s NEPA review. The Commission notes that environmental report need not include a discussion of assessment of

the benefits and impacts of constructing and operating the manufactured reactor or an evaluation of alternative energy sources, under § 52.163 and § 51.54.

Under § 51.54, the environmental report for a manufacturing license must address the costs and benefits of SAMDAs that could be incorporated into the design, and the bases for not including SAMDAs into the design. The SAMDA information that must be included is essentially the same information that must be provided to support an application for a standard design certification. However, if the application references a standard design certification, § 51.54 provides that the manufacturing license's environmental report need not include the SAMDA evaluation. In such a case, the SAMDA determination in the EA for the referenced design certification would have finality in the manufacturing license proceeding, in accordance with § 52.63. The narrowed scope of a manufacturing license environmental report referencing a design certification under § 51.54 is repeated for clarity in § 52.158(c)(2).

§ 52.159 Standards for review of applications.

This new section is analogous to the “standards for review of applications” sections in subparts A through C of part 52 (e.g., §§ 52.18, 52.48, 52.81). Section 52.159 identifies the regulations that the NRC will use in reviewing an application for a manufacturing license. The NRC recognizes that reactors to be manufactured under a manufacturing license may incorporate design features which are inconsistent with current requirements in 10 CFR Chapter 1, and may require exemptions from current requirements. Such exemptions would be granted as part of the NRC's issuance of the manufacturing license, together with alternative requirements (analogous to the “applicable regulations” provisions in the current design certifications rules, 10 CFR part 52, appendices A-D, Section V).

§ 52.161 RESERVED

This section is reserved to accommodate any new requirements on the application process for manufacturing license which the NRC may adopt in the future.

§ 52.163 Administrative review of applications; hearings.

This new section is analogous to the “administrative review of applications” sections in subparts A through C of part 52 (e.g., §§ 52.21, 52.51, 52.85). Section 52.163 specifies that the procedural requirements in 10 CFR part 2 apply to the NRC’s processing of an application for a manufacturing license, including docketing of the initial application.

Section 52.163 reiterates the § 2.105 requirement that the NRC publish in the *Federal Register* a notice of proposed action on the application. Apart from the required *Federal Register* notice, the Commission also expects to publish on the NRC’s Web site notice of docketing of the application and the opportunity to intervene in the proceeding, consistent with the Commission’s discussion in the 2004 final part 2 rulemaking (January 14, 2004; 69 FR 2182, 2198-99). The section makes clear, consistent with § 51.54, that the environmental report submitted by the manufacturing license applicant need not contain an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources.

Finally, this section indicates that the hearing on the manufacturing license application will be governed by the procedures in part 2, subparts C, G, L, and N. The Commission notes that although subpart G is listed in this paragraph, it is unlikely that there would be contentions meeting the criteria in § 2.310 (and reiterated in § 2.700) for conduct of the hearing under subpart G. This is because the primary focus of the manufacturing license proceeding is on the

adequacy of the design to be manufactured, and the nature of issues which are most likely to be raised on the design would not ordinarily involve issues of material fact relating to either: (1) the occurrence of a past activity, where the credibility of an eyewitness may reasonably be expected to be at issue; or (2) issues of motive or intent of the party or eyewitness which are material to the resolution of the contested matter.

§ 52.165 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

This new section is analogous to the “Referral to the Advisory Committee on Reactor Safeguards” sections in subparts A through C of part 52 (e.g., §§ 52.21, 52.53, 52.87). It provides that the ACRS will have the same role with respect to manufacturing licenses that it has for other nuclear power plant licenses, in that it will report on those portions of the application which concern safety.

§ 52.167 Issuance of manufacturing license.

This new section is analogous to the “issuance” sections in subparts A through C of part 52 (e.g., §§ 52.24, 52.54, 52.97). Paragraph (a) sets forth the timing of issuance of a manufacturing license and the findings that the Commission must make in order to issue the manufacturing license. The findings that must be made are similar to those necessary to issue a construction permit, inasmuch as construction is analogous to manufacturing. The Commission notes that it reserves the right to withhold issuance of the manufacturing license, even if all the rules and regulations of the Commission have been satisfied, based on public health and safety or common defense and security information or considerations not adequately addressed in the Commission’s rules and regulations.

Paragraph (b) identifies the specific limitations that the Commission will include in each manufacturing license. They include technical specifications for the operation of each manufactured reactor, site parameters, design characteristics, and interface requirements, which are to be used by the applicant for and holder of the license referencing the use of the manufactured reactor(s). Ordinarily, the limitations to be included in the manufacturing license would be derived from the manufacturing license application, but the NRC may modify the proposed limitations based upon the NRC's review.

Paragraph (c) restricts the holder of the manufacturing license from transporting or allowing to be removed from the place of manufacture the manufactured reactor except to the site of a licensee who holds either a construction permit or combined license referencing the use of that manufactured reactor.

§ 52.169 RESERVED

This section is reserved to accommodate any new requirements on either the issuance of, or activities authorized under a manufacturing license which the Commission may adopt in the future. Any new requirements adopted after issuance of a manufacturing license, which are made applicable to that manufacturing license, would have to satisfy the finality restrictions in § 52.171.

§ 52.171 Finality of manufacturing licenses; information requests.

This new section is analogous to the variously entitled sections addressing finality and special backfitting protections which are in subparts A through C of part 52 (e.g., §§ 52.39,

52.63, 52.98),¹² but is more generally modeled on the finality provision for standard design certifications. In general, paragraph (a) addresses backfitting and finality restrictions on the NRC, paragraph (b) addresses finality and standardization restrictions applicable to the licensee (*i.e.*, the holder the manufacturing license), and paragraph (c) establishes restrictions on certain NRC information collections with respect to the manufacturing license.

Paragraph (a)(1) states that the Commission may not modify, rescind, or impose new requirements on the design of a nuclear power reactor being manufactured, or new requirements for the manufacture of the of the nuclear power reactor, unless the Commission determines that a modification is necessary to either bring the design or the manufacture of the reactor into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security. This restriction on the Commission applies, *inter alia*, in construction permit, operating license, and combined license proceedings which reference the use of the manufactured reactor. It also applies in any enforcement proceeding initiated by the NRC, or in a rulemaking which proposes to apply new or changed requirements to reactors which have already been manufactured, as well as any reactors yet to be manufactured under the manufacturing license. However, the restrictions in paragraph (a)(1) do not apply to NRC information requests directed at either the manufacturing license holder, or to any holder of a license referencing the use of a manufactured reactor; such information requests are governed by paragraph (c) of this section.

Paragraph (a)(2) provides that any modification to the design of a manufactured nuclear power reactor which is imposed by the Commission under paragraph (a)(1) of this section will

¹²The finality provision in § 52.83 performs a different function than the finality sections cited above, in that it points back to, and thereby re-emphasizes, the primary finality provisions for each license or regulatory approval mechanism in part 52, e.g., the finality provision in § 52.39 for early site permits.

be applied to all reactors manufactured under the license, including those that have already been manufactured, transported, sited, and are in operation. The only exception would be for those reactors to which the Commission-ordered modification had been rendered technically irrelevant by action taken under paragraph (b) of this section, *i.e.*, either the holder of the manufacturing license has requested a change to the design approved in the manufacturing license (which ordinarily would apply only to reactors manufactured *after* Commission approval of the change), or the holder of a license referencing the use of the manufactured reactor has obtained Commission approval for a change to the design of the specific manufactured reactor(s) utilized by that licensee.

Paragraph (a)(3) delineates the nature of finality associated with the referencing of a manufactured reactor in subsequent NRC licensing proceedings. This paragraph provides that finality is accorded to those matters resolved in the proceeding on the issuance or renewal of the manufactured reactor. These matters resolved include the adequacy of the design of the manufactured reactor, the acceptability and completeness of the ITAAC required by § 52.158(b)(1) to be performed by the licensee operating the reactor, and the acceptability of the § 52.158(a) PRA. The matters resolved also include the SAMDA evaluation prepared by the Commission in compliance with its obligations under NEPA. This finality extends to both the Commission's determinations with respect to specific SAMDA features included in the design of the manufactured reactor, as well as the Commission's determinations regarding the lack of need for any other SAMDA features. Finality is accorded in the following situations: (1) issuance of a construction permit, operating license, combined license; (2) any hearing under § 52.103; and (3) enforcement hearings other than those proceedings initiated by the Commission under paragraph (a)(1).

Paragraph (b)(1) requires the holder of a manufacturing license to seek a prior NRC review and approval for any change to the design of the nuclear power plant authorized to be

manufactured. The holder of the manufacturing license may not make a change to the approved design for manufacture through the provisions of § 50.59. A request for a change to the approved design must be in the form of a license amendment application, and the application will be processed in accordance with §§ 50.90 through 50.92. The Commission notes, however, that the procedures for no significant hazards consideration (NSHC) are not applicable to manufacturing licenses, inasmuch as Section 189.a.(2) of the AEA, which is the statutory authority for these procedures, does not apply to manufacturing licenses.

Paragraph (b)(2) requires a holder of a license referencing the use of a manufactured reactor, who wishes to depart from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor, to seek a departure from the NRC. The manner in which a departure is granted depends upon the timing of the request. If a departure requested as part of the initial combined license application, the departure would be treated as part of the application and issued as part of the combined license. By contrast, if the same departure were sought after the combined license had been issued, then the licensee must apply for the departure in the form of a license amendment. The criteria for granting the departure is the exemption criterion in § 52.7; however, the departure itself is *not* considered an exemption (unless, of course, the departure also involves a non-compliance with an underlying Commission regulatory requirement in 10 CFR Chapter 1). Thus, the Commission will not approve a departure unless the Commission finds, in addition to the routine exemption criteria in § 52.7, that special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. As explained earlier, these limitations are intended to maintain the standardization of manufactured reactors in operation to the extent practicable. The licensee may not depart from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor through the provisions of § 50.59.

Paragraph (c), which is analogous to §§ 52.39(d), 52.98(g), and 52.145(c), provides that NRC information requests must be evaluated before issuance to ensure that the burden to imposed by the information request is justified in view of the potential safety significance of the issue to be addressed, except when the information requests seeks to verify compliance with the current licensing basis of either the manufacturing license or the manufactured reactor. This paragraph applies to information requests directed at either the holder of the manufacturing license or the holder of a license referencing the use of a manufactured reactor. Information requests may be in the form of a new rule requiring submission of information (*i.e.*, a new information collection and reporting requirement), or in the form of a NRC staff request for information. Information requests by the staff must be in accordance with 10 CFR 50.54(f) and must be approved by the EDO or his or her designee before the request may be issued.

§ 52.173 Duration of manufacturing license.

This new section is analogous to the variously-entitled sections addressing duration (term) of each regulatory process in subparts A through C of part 52 (*e.g.*, §§ 52.33, 52.61, 52.104). Under § 52.173, a manufacturing license may be issued for not less than 5 nor more than 15 years. Manufacturing of a new reactor may not commence less than 3 years before the expiration of the manufacturing license, even though a timely application for renewal has been filed in accordance with § 52.177. However, if a timely application for renewal of the manufacturing license has been docketed, manufacturing of uncompleted reactors whose manufacture commenced 3 years or more before the expiration date, may continue past the date of expiration of the license until the NRC acts upon the renewal application, consistent with the “Timely Renewal” doctrine of the Administrative Procedures Act. The NRC believes that timely renewal protection should only be provided to those applications which are of sufficient

quality to be docketed. This is consistent with the requirement in § 2.109(b) requiring filing of a “sufficient” application for renewal of operating licenses as a prerequisite for the applicability of the timely renewal protection.

§ 52.175 Transfer of manufacturing license.

This new section is analogous to the variously entitled transfer sections in subparts A and C of part 52 (*e.g.*, §§ 52.28, 52.105).¹³ Section 52.175 provides that a manufacturing license may be transferred in accordance with § 50.80, which constitutes the Commission’s common procedures and criteria governing transfers of nuclear power plant licenses. The matters to be addressed in a transfer are limited to the matters identified in § 50.80(b), and the transfer would not be an opportunity for the Commission to reconsider safety and environmental matters previously resolved, or to address new safety matters other than the narrow scope of matters identified in § 50.80(b).

§ 52.177 Application for renewal.

This new section is analogous to the “application for renewal” sections in subparts A through C of part 52 (*e.g.*, §§ 52.29, 52.57, 52.107). Section 52.177 sets forth the content of an application for renewal, specifies the administrative requirements governing the application, addresses the effectiveness of a manufacturing license during the period of NRC’s consideration of the renewal application, summarizes how an interested person may request a

¹³A standard design certification is a rule, rather than a license. Accordingly, there is no “holder” of a standard design certification rule and no need for a provision addressing “transfer” of a standard design certification rule.

hearing on the renewal, and addresses the referral of the renewal application to the ACRS and the Commission's expectations with respect to the ACRS report on the application.

§ 52.179 Criteria for renewal.

This new section is analogous to the "criteria for renewal" sections in subparts A and B of part 52 (e.g., §§ 52.31, 52.59).¹⁴ Section 52.179 provides that the Commission may grant renewal of a manufacturing license if the Commission determines that the license complies with the relevant provisions of the AEA, the Commission's regulations applicable and in effect at the time the manufacturing license was originally issued, and any new requirements which the Commission imposes which: (1) are necessary for reasonable assurance of adequate protection to public health and safety or common defense and security; (2) are necessary for compliance with Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; or (3) represent a substantial increase in overall protection of the public health and safety or common defense and security and the direct and indirect costs of implementation are justified in light of the increased protection. These "backfitting" restrictions are similar to - if somewhat narrower than - the backfitting restrictions applicable to renewal of standard design certification rules under subpart B of this part.

Reasonable assurance of adequate protection to public health and safety and common defense and security is provided under this regulatory approach, inasmuch as paragraph (b) allows the Commission to impose new requirements which are necessary for common defense

¹⁴Subpart C does not contain a "criteria for renewal" provision, inasmuch as the renewal would be governed by 10 CFR part 54, see § 52.107. Part 54 contains a provision, § 54.29, setting forth the standards for issuance of renewed licenses.

and security, or are necessary for compliance with the Commission's regulations and orders applicable an in effect at the time the manufacturing license was originally issued.

§ 52.181 Duration of renewal.

This new section is analogous to the "duration of renewal " sections in subparts A and B of part 52 (e.g., §§ 52.33, 52.61).¹⁵ Section 52.181 specifies the term of a renewed manufacturing license as not less than 5 nor more than 15 years from the date of expiration of the *prior* manufacturing license. Thus, a holder of a manufacturing license with an original term of 15 years, who is granted a 15-year renewal of the manufacturing license 4 years before expiration of the license, will obtain a renewed manufacturing license of 19 years, representing a 15-year term of the renewed license plus the 4 years remaining on its original license.

Subpart G - Reserved

This subpart is reserved for future use by the Commission.

Subpart H - Enforcement

This subpart contains two provisions, § 52.301 and § 52.303, which are comparable to former § 52.111 and § 52.113, and are analogous to provisions contained in other parts of 10 CFR Chapter 1 imposing requirements on regulated entities.

¹⁵Subpart C does not contain a "duration of renewal" provision, inasmuch as the renewal would be governed in all respects by 10 CFR part 54, see § 52.107. Part 54 contains a provision, § 54.31, governing the duration of renewed licenses.

Section 52.301 reiterates, and provides notice to licensees and applicants under part 52 of the Commission's authority to obtain injunctions or other court orders for the violations enumerated in this paragraph.

Section 52.303 provides notice to all persons and entities subject to part 52 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 52. The regulations for which criminal penalties apply are limited to those which establish either a regulatory obligation or prohibition. Most of the regulations in part 52 are procedural or administrative in nature, and therefore were listed in § 52.113 as not being subject to criminal sanctions. The regulations in part 52 which *are* subject to criminal sanctions are §§ 52.4 (Deliberate misconduct), 52.5 (Employee protection), 52.6 (Completeness of information), 52.25 (Extent of activities permitted), 52.35 (Use of site for other purpose), 52.91 (Authorization to conduct site activities), and 52.110 (Termination of license).

APPENDIX A - U.S. ADVANCED BOILING WATER REACTOR

Refer to the section-by-section discussion in the final rule dated May 12, 1997 (62 FR 25800).

APPENDIX B - THE SYSTEM 80+ DESIGN

Refer to the section-by-section discussion in the final rule dated May 21, 1997 (62 FR 27840).

APPENDIX C - THE AP600 DESIGN

Refer to the section-by-section discussion in the final rule dated December 23, 1999 (64 FR 72002).

APPENDIX D - THE AP1000 DESIGN

Refer to the section-by-section discussion in the final rule dated January 27, 2006 (71 FR 4464).

APPENDIX N: COMBINED LICENSES FOR NUCLEAR POWER REACTORS OF IDENTICAL DESIGN

Appendix N of part 52 contains the Commission's procedures which may be used by one or more applicants for combined licenses under part 52, where the applications seek to construct and operate nuclear power reactors of identical design to be located at multiple sites. The comparable procedures governing applications for construction permits and operating licenses using identical nuclear power reactor designs remain in appendix N of 10 CFR part 50. Hearings for applications filed under appendix N in part 52, as well as part 50, are governed by subpart D of part 2. Thus, appendix N and subpart D of part 2 are integral to each other.

The regulations in appendix N of part 52 apply in two situations: (1) where the same applicant seeks a combined licenses at different sites utilizing the identical reactor design; and (2) where two or more different applicants each seek combined licenses at different sites utilizing the identical reactor design. In either situation, there is an identical reactor design.

The Commission has deliberately used the term, “nuclear power reactor,” in appendix N and subpart D of part 2 - as distinguished from the term, “nuclear power plant” - to make clear that the site-specific elements, such as the service water intake structure or the ultimate heat sink, need not be identical in order for appendix N and subpart D to apply.

The Commission has conformed appendix N and subpart D of part 2 to use the term, “identical” nuclear power reactor design, and removed references to “duplicate” and “essentially identical.” For purposes of appendix N and subpart D of part 2, designs for reactors are “identical,” even if individual licensees request plant-specific departures or exemptions from a referenced standard design certification (or application). However, those plant-specific departures or exemptions are not part of the “common design.” Therefore, the NRC’s review of those departures and exemptions, as well as NRC hearings on those departures and exemptions, would be conducted separately as part of the safety review of each individual application, and would not be part of the hearing on the common design which would be conducted under subpart D of part 2.

Section 1

This is a new section specifying that its provisions apply to applicants for combined licenses under subpart C of part 52. Appendix N of part 50 would apply to applicants for construction permits and operating licenses who use identical reactor designs.

Section 2

This section, which is analogous to and derived from former § 2 of appendix N, specifies that each application submitted under this appendix must be submitted in accordance with the

delineated Commission filing requirements. In addition, to ensure that the NRC is clearly informed that the applicants wish to have their application processed under appendix N and subpart D of part 2, this section requires: (1) that each application state the applicant's intent that the application be processed by the NRC under appendix N; and (2) that all of the applications to be treated together under this appendix be listed in each application. All of the applications must be filed simultaneously, which will facilitate NRC's administrative handling and technical review of the applications, as well as efficient conduct of the hearing process.

Section 3

This section, which is analogous to and derived from former § 3 of appendix N, specifies that combined license applications submitted under this appendix must include all of the information required to be submitted in a combined license application in §§ 52.77, 52.79, and 50.80(a) and (b), but makes clear that each of the applications must identify the common design. The common design may be (but is not limited to) a standard design certification under subpart B of part 52, a standard design approval, a "common custom design," or a manufactured reactor.

The FSAR for each application must either incorporate by reference or include the FSAR for the common design, including, as applicable, the FSAR for the referenced design certification or manufactured reactor. "Physically include," means that the FSAR may not simply reference to the common FSAR; the information from the referenced FSAR must be included within each application's FSAR.

Section 4

This is a new section specifying that each application must submit an environmental report which complies with the applicable provisions of part 51 with respect to the content of environmental reports. As an alternative, this section provides that one or more of the applicants' environmental reports may incorporate by reference a single environmental report describing the environmental impacts of the common design at each of the sites.

Section 5

This is a new section specifying that, upon a determination that each application is acceptable for docketing, each application will be docketed and a notice of docketing will be published in the *Federal Register* in accordance with 10 CFR 2.104. The notice of docketing must state that the application will be processed under the provisions of appendix N. Separate notices of docketing are contemplated, so that a problem with acceptance review of one application will not prevent the docketing and initiation of the NRC's technical review of the other applications determined to be sufficient and acceptable for docketing. This could occur, for example, if information, submitted by an applicant which is unrelated to the common design, is determined by the NRC to be insufficient. However, if the applications are determined to be acceptable for docketing, § 5 provides the Commission with the discretion to publish a single notice of docketing for those applications.

Section 6

This is a new section which provides that the NRC will prepare a separate draft and final EIS for each of the applications. Scoping may be conducted simultaneously but need not be conducted jointly (e.g., scoping for an application at site 1 need not be conducted as part of the

same process as the scoping for an application for site 2), at least with respect to site-specific environmental issues. However, for environmental issues related to the common design, the NRC has the discretion to conduct joint scoping. The NRC staff is not, however, required to prepare a joint environmental impact statement for the common design.

This section also addresses the content of an EIS when the applications reference either a standard design certification or the use of a manufactured reactor of common design. In either case, the NRC has already prepared and finalized an EA which addresses SAMDAs. This SAMDA analysis is accorded finality under the provisions of §§ 52.63 and 52.171, respectively. Therefore, the EIS for each of the applications must reference the relevant environmental assessment containing the SAMDA analysis.

Section 7

This section, which is analogous to and derived from former § 1 of appendix N, provides direction to the ACRS with respect to their report on each of the combined license applications. The ACRS must issue a separate report on the safety of the common design, except in those instances where the applications are referencing either a standard design certification or manufactured reactor (of common design). In addition, the ACRS must issue a separate report for each application. This report must be limited to those matters which are not relevant to the common design. This will facilitate the NRC's licensing process by eliminating overlap and ensuring that the ACRS reports are carefully focused on the relevant safety issues.

Section 8

This is a new section, which provides that the Commission shall designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters (*i.e.*, SAMDAs) relating to the common design. The presiding officer will conduct the hearing in accordance with subpart D of part 2. The presiding officer is required to issue a separate partial initial decision on matters relevant to the common design, consistent with 10 CFR 2.405 in subpart D of part 2. Appeals of the partial initial decision are governed by 10 CFR 2.341, as provided by 10 CFR 2.405. The NRC also notes that issues on the contested design may not be relitigated in a different phase of the hearing except on the basis for significant new information that substantially affects the conclusion(s) reached at the other phase or other good cause. See 10 CFR 2.406.

APPENDIX Q TO PART 52—PRE-APPLICATION EARLY REVIEW OF SITE SUITABILITY ISSUES

Appendix Q of part 52 contains the Commission's procedures which may be used by an applicant to request a review by the Office of New Reactors or the Office of Nuclear Reactor Regulation of selected siting issues separately from and prior to an application for an early site permit or combined license. The results of an early site review are not subject to a hearing by the Atomic Safety and Licensing Board, but safety issues will be reviewed by the Advisory Committee on Reactor Safeguards.

Sections 1 and 2

These paragraphs explain who can file and how to file an application for an early site review, and how to set forth the type of information to be included in the application. The

application must provide sufficient information to support the NRC staff's review of the site suitability issues. The site suitability issues can involve site safety, environmental impact, or both. The application must list, to the extent possible, any long-range objectives for ultimate development of the site, describe any site selection process used, and explain what consideration, if any, was given to alternative sites.

Section 3

This paragraph explains the process for providing notice of the application. This paragraph also explains that any site safety issues for which the applicant requests staff review will be referred to the Advisory Committee on Reactor Safeguards for their review.

Section 4

This paragraph describes the contents of an NRC staff site report on the issues for which the applicant requests review. This paragraph also describes the process for issuing an NRC staff site report, including a requirement for the NRC to publish a notice of the availability of the report in the *Federal Register* and to send a copy of the report to State officials.

Section 5

This paragraph describes the finality for a staff site report and states that a staff site report may be incorporated by reference in an application of an early site permit or a combined license. The conclusions of a staff site report will be re-examined by the staff where 5 years or

more have elapsed between the issuance of the report and its incorporation by reference in an early site permit of combined license application.

Section 6

This paragraph states that issuance of a staff site report does not constitute a commitment to issue a permit or license, to permit site work under § 50.10(e), or in any way affect the authority of the Commission, the Atomic Safety and Licensing Appeal Panel, Atomic Safety and Licensing Board Panel, and other presiding officers in any proceeding under subparts F and/or G of part 2 of this Chapter.

Section 7

This paragraph sets forth the criteria that the NRC staff will use in determining whether to perform a review of a site suitability issue, as the applicant's requests relate to the requirements in 10 CFR part 2 and subpart A of part 51.

VII. Availability of Documents.

The NRC is making the documents identified below available to interested persons through one or more of the following methods as indicated.

Public Document Room (PDR). The NRC Public Document Room is located at 11555 Rockville Pike, Rockville, Maryland.

Rulemaking Web site (Web). The NRC's interactive rulemaking Web site is located at <http://ruleforum.llnl.gov>. These documents may be viewed and downloaded electronically via this Web site.

NRC's Public Electronic Reading Room (EPDR). The NRC's electronic public reading room is located at www.nrc.gov/reading-rm.html.

The NRC staff contact. Nanette V. Gilles, Mail Stop O-4D9A, Washington, DC 20555-0001, 301-415-1180.

Document	PDR	Web	EPDR	NRC Staff
Part 52 Rule, Cross-Reference Tables		X	ML062550246	X
Comments received	X	X	X	
Comment Summary Report			ML062920405	
Regulatory Analysis	X	X	ML062650391	X
Regulatory History Index for the proposed July 2003 rule			ML032810026	
Regulatory History Index For the March 13, 2006, proposed rule			ML062080575	

VIII. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" which became effective on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC or adequacy category, Health and Safety (H&S). Category A includes program elements that are

basic radiation protection standards or related definitions, signs, labels, or terms necessary for a common understanding of radiation protection principles and should be essentially identical to those of NRC. Category B includes program elements that have significant direct transboundary implications and should be essentially identical to those of the NRC. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and do not need to be adopted by Agreement States. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act, as amended, or provisions of Title 10 of the Code of Federal Regulations and should not be adopted by Agreement States. Category H&S are program elements that are not required for compatibility, but have a particular health and safety role in the regulation of agreement material and the State should adopt the essential objectives of the NRC program elements. The revisions in this final rule are categorized as follows:

List of Changes 10 CFR Part 52 Final Rulemaking		
Sections	Description-New, Changes	Compatibility Designation
10 CFR Part 2 - Rules of practice for domestic licensing proceedings and issuance of orders		
Subpart A		
2.1	Scope	[D]
		A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.3	Initial decision in contested proceedings on facility operating license applications; immediate effectiveness of certain decisions.	[D]
		A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.4	Definitions	
	Contested proceedings	[D]
		A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
	License	[D]
		A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This definition appears in 10 CFR 20.1003. For purposes of compatibility, States should use the language of the Part 20 definition, which is assigned a Compatibility Category D.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
	Licensee	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This definition appears in 10 CFR 20.1003. For purposes of compatibility, States should use the language of the Part 20 definition, which is assigned a Compatibility Category D.
2.100	Scope of subparts	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.101	Filing of applications	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.102	Administrative review of application	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.103	Action on application for byproduct, source, etc.	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.104	Notice of hearing	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.105	Notice of proposed action	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.106	Notice of issuance Added notice for COL in <i>Federal Register</i> (FR)	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.107	Withdrawal of application	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.108	Denial of application for failure to supply information	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.109	Effect of timely renewal application	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.110	Filing and administrative action on submittals for standard design approval or early review of site suitability issues	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.111	Prohibition of sex discrimination	[D]	States may adopt similar provisions as a part of their regulatory programs.
Subpart B 2.2	Scope of subpart	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.201	Notice of violation	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.202	Orders	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.203	Settlements and compromise	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.204	Demand for information	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.205	Civil penalties	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.206	Request for action under this subpart	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
Subpart C 2.390	Public inspections, exemptions, requests for withholding	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
Subpart D 2.400	Scope of subpart	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.401	Notice of hearing on applications to subpart G for part 52 for construction permits (CPs)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.402	Separate hearings on separate issues; consolidation of hearings	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.403	Notice of action on applications for operating licenses (OLs) to subpart G of part 52	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.404	Hearings on application for OLs pursuant to appendix N part 52	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.405	Initial decisions in consolidated hearings	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.406	Finality of decisions on separate issues	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.407	Applicability of other sections	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Subpart E 2.500	Scope of subpart	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.501	Notice of hearing on application under subpart F of part 52 for a license to manufacture nuclear power reactors	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
Subpart F 2.600	Scope of subpart	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.601	Applicability of other sections	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.602	Filing fees	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.603	Acceptance and docketing of application for early review of site suitability issues	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.604	Notice of hearing on application for early site review of site suitability issues	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.605	Additional considerations	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.606	Partial decision on site suitability issues in construction permit	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.621	Acceptance and docketing of application for early review of site suitability issues in a combined license proceeding	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.623	Notice of hearing on application for early review of site suitability issues in combined license proceeding	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.625	Additional considerations	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking			
Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.627	Partial decision on site suitability issues in combined license proceeding	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other
2.629	Finality of partial decision on site suitability issues in combined license proceeding	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other
Subpart H 2.800	Scope of subpart Revised to include design certification (DC) application	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.801	Initiation of rulemaking	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.811	Filing of standard design certification (SDC) application; required copies	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

List of Changes 10 CFR Part 52 Final Rulemaking			
Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.813	Written communications	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.815	Docketing and acceptance review	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.817	Withdrawal of application	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.819	Denial of application for failure to supply information	[D]	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 10 - Criteria and procedures for determining eligibility for access to restricted data or national security information or an employment clearance criteria			
10.1	Purpose	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10.2	Scope	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10 CFR Part 19 - Notices, Instructions and Reports to Workers: Inspection and Investigations			
19.1	Purpose	D	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
19.2	Scope	D, except portions of (a)(1), (a)(2), (a)(3), and (a)(4) are NRC	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. Paragraphs (a)(1), (a)(2), (a)(3), (a)(4) reference regulatory activities reserved to the NRC (10 CFR Parts 50, 52, 54, 60, 63, 72 and 76) and those provisions are designated as a Compatibility Category NRC, and should not be adopted by States.
19.3	Definitions Regulated activities	D except portions of the definition are designated as NRC	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. Those portions of the definition that reference 10 CFR Parts 50, 52, 54, 60, 63, 72 and 76 are designated as a Compatibility Category NRC, and should not be adopted by States.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
	Regulated entities	D except portions of the definition are designated as NRC	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. Those portions of the definition that reference NRC areas of authority are designated as a Compatibility Category NRC, and should not be adopted by States.
Worker		C	A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. This provision is currently designated a Compatibility Category C, and the essential objectives of these provisions should be adopted by an Agreement State.
19.11	Posting of notices to workers	C, except portions of the provision are designated as NRC	A State should provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. This provision is currently designated a Compatibility Category C, and the essential objectives of these provisions should be adopted by an Agreement State. Those portions of the provision that reference NRC areas of authority are designated as a Compatibility Category NRC, and should not be adopted by States.
19.14	Presence of representatives of licensees and regulated entities, and workers during inspections	C, except portions of the provision are designated as NRC	A State should provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. This provision is currently designated a Compatibility Category C, and the essential objectives of these provisions should be adopted by an Agreement State. Those portions of the provision that reference NRC areas of authority are designated as a Compatibility Category NRC, and should not be adopted by States.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
19.20	Employee protection	D, except portions of the provision are designated as NRC	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. Those portions of the provision that reference NRC areas of authority, e.g., 10 CFR Parts 50, 52, 54, 60, 63, 72, and 76, are designated as a Compatibility Category NRC, and should not be adopted by States.
19.31	Application for exemptions	D, except portions of the provision are designated as NRC	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
19.32	Discrimination prohibited	D	A State may adopt similar provisions consistent with their regulatory authority.
10 CFR Part 20 - Standards for protection against radiation			
20.1002	Scope	D, except portions of the provision are designated as NRC	A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. The State's provisions should not address areas reserved to the NRC pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. Those portions of the provision that reference NRC areas of authority, e.g., 10 CFR Parts 50, 52, 54, 60, 63, 72, and 76, are designated as a Compatibility Category NRC, and should not be adopted by States.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
20.1401	General provisions and scope	C, except portions of the provision are designated as NRC	A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. Portions of this provision is currently designated a Compatibility Category C, and the essential objectives of these provisions should be adopted by an Agreement State. Those portions of the provision that reference NRC areas of authority are designated as a Compatibility Category NRC, and should not be adopted by States.
20.1406	Minimization of contamination	C, except portions of the provision are designated as NRC	A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. Portions of this provision is currently designated a Compatibility Category C, and the essential objectives of these provisions should be adopted by an Agreement State. Those portions of the provision that reference NRC areas of authority are designated as a Compatibility Category NRC, and should not be adopted by States.
20.2203	Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.	C - paragraphs (a), (b) D - paragraph (d) NRC-paragraph (c)	A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act), and are consistent with their regulatory authority. Portions of this provision is currently designated a Compatibility Category C, and the essential objectives of these provisions should be adopted by an Agreement State. Those portions of the provision that reference NRC areas of authority are designated as a Compatibility Category NRC, and should not be adopted by States.

List of Changes 10 CFR Part 52 Final Rulemaking		
Sections	Description-New, Changes	Compatibility Designation
Comments Regarding Compatibility Designation		
10 CFR Part 21 - Reporting of defects and noncompliance		
21.2	Scope	N/A
		The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.3	Definitions	N/A
		The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.5	Communications	N/A
		The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
21.6	Posting requirements	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.7	Exemptions	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.8	Information collection requirements - OMB approval	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
21.21	Notification of failure to comply or existence of a defect and its evaluation	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.31	Procurement documents	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.41	Inspections	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
21.51	Maintenance and inspection of records	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.61	Failure to notify	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.62	Criminal penalties	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10 CFR Part 25 - Access authorization for licensee personnel			
25.35	Classified visits	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
10 CFR Part 26 - Fitness for duty programs			
26.2	Scope	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
26.10	General performance objectives	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
10 CFR Part 50 - Domestic licensing of production and utilization facilities			
50.12 and new §§	Specific exemptions	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.23	Construction permits	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.30	Filing of application; oath or affirmation	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.33	Contents of applications; general information Revise 50.33(a)(1)-(3) & appendix L to part 50 to address combined license (COL)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.34	Contents of CP and OL applications; technical info	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.36(a)	Technical specifications on effluents from nuclear power reactors	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.40	Common standards	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amend The ed, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.41	Additional standards for class 104 licenses	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.42	Additional standards for class 103 licenses	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.43	Additional standards and provisions affecting class 103 licenses for commercial power	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.45	Standards for CP, COL, and manufacturing license (ML)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.46	Acceptance criteria for emergency core cooling systems for light water reactor (LWR)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.47	<p>Emergency plans</p> <p>Revise 50.47(a)(1) & 50.47(a)(1)(ii)</p> <p>Revise 50.47(c)(1) to include early site permit (ESP) add new 50.47(e) for COL</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
50.48	<p>Fire protection</p> <p>Revise (a)(1) for COL & Operating license</p> <p>Revise (a)(4) for DA, DC, and ML</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
50.54 Appendix E	<p>Conditions of licenses</p> <p>Exclude manufacturing license</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
50.55	<p>Conditions of CP</p> <p>Modify to address its' applicability to other types of licenses as well</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.55a	Codes and standards Modify to address its applicability to other types of licenses as well	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.59	Changes, tests, and experiments	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.61	Fracture toughness requirements for protection against pressurized thermal shock events	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.63	Loss of all alternating current power	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.65	Requirements for monitoring effectiveness of maintenance at nuclear power plants	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.69	Risk informed categorization and treatment of structures, systems, and components for nuclear power reactors	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.70	Inspections Applicability to ESP holders	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.5, 50.7, 50.9	Wrongdoing, accuracy of information, and employee protection	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.71	Maintenance of records, making of reports Added the same requirement for SDA, SR, and DC Revise 50.71 (e) for COL, ML for updating final safety analysis report (FSAR)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.73	License event report system	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.75	Decommissioning funding assurance	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.78	Installation information and verification	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.8	Transfer of license (a) & (b)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.81	Creditor regulations	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.90	Application for amendment of license or construction permit To clarify applicability	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.91	Notice for public comment; State consultation For ESP, State to be notified	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.92	Issuance of amendment	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.100	Revocation, suspension, modification of licenses. Clarifying its intent for ESP, COL, and ML	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
50.109	Backfitting Requesting public comments on applicability of this rule on SDC rules, ESP review, COL, ML, & DDL	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
50.120	Training and qualification of nuclear power plant personnel	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendix A	General Design Criteria-Nuclear Power Plants Applicable to COL, DA, DC, ML as well as for CP	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendix B	QA criteria for nuclear power & fuel reprocessing plants Applicable to ES review and ESP	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendix C	Financial qualifications for CP and COL applicants	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendix E	Emergency Preparedness for production and utilization facilities	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
Appendix I	Numerical guides for design objectives of light-water-cooled (LWC) reactors	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendix J	Primary reactor containment leakage testing for water-cooled reactors Applicability for COL	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendix L	Information to AG for antitrust review for CP, IOL and COL- Discussed in §§ 50.33	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendices M, N, O, & Q	Moved to Part 52		The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
	Antitrust responsibilities	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking		
Sections	Description-New, Changes	Compatibility Designation
10 CFR Part 51	Environmental protection regulations for domestic licensing and related regulatory functions	NRC FOR ALL SECTIONS
		Comments Regarding Compatibility Designation The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
10 CFR Part 52 - Additional licensing processes for nuclear power plants		
General Provisions		NRC
		The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.3	Definitions	NRC
		The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
	Applicability of 10 CFR Chapter 1 provisions	NRC
		The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.5	Interpretations	NRC
		The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
-	Specific exemptions	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	Combining licenses	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	Jurisdictional limitations	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.9	Deliberate Misconduct Deleted & replaced "Attacks and-"	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	Attacks and destructive acts by enemies of United States and defense activities	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.8	Information collection - OMB approval	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Subpart A - Early Site Permits (ESP), Standard Design Certifications (SDC), and Combined licenses (COL) for Nuclear Power Plants			
52.11	Scope of subpart	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.13	Relationship to subpart F 10 CFR Part 52 and Appendix Q	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.15	Filing of application	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	Contents of application - general information	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.17(a)(1)	<p>Contents of application</p> <ol style="list-style-type: none"> 1. Include range of units to be built 2. Delete reference to 50.34 (seismic engineering) 3. Address security plans 4. Add a QA plan for future design/construction 5. Add discussion of multiunits sites to address safety of SSC during construction 6. Add evaluation against review guidance 	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
52.17(b)(1)	<p>Include site characteristics for emergency plan (EP) and/or mitigation Requirements, emergency plans</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
52.17(b)(2)(i)(ii)	<p>In accordance with 50.47 and appendix E to part 50</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
-	Applications to include ITAAC	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.18	Standard for review of application in accordance with part 51	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.21	Administrative review of application; hearings	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.23	Referral to the ACRS	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.24	Issuance of an early site permit	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
-	Transfer of early site permit	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.25	Extent of activities permitted	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.27	Duration of permit	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.29	Application for renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.31	Criteria for renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.33	Duration of renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.35	Use of site for other purposes	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.37	Reporting of defects and noncompliance; revocation	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.39	Finality of early site permit determination	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	Updating of emergency preparedness Updating requirement for referencing an ESP or COL	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
Subpart B - Standard Design Certifications			
52.41	Scope	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.43(c), 52.45(c), 52.47(b)(2)(ii)	Relationship to others Removed requirements of FDA from design certification	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.45	Filing of application	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.46	Contents of application; general information	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.47(a)(2), 52.47(a)(3)	Contents of applications; technical information Amend to clarify the PRA to be full scope	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.47(b), 52.79(d), Appendix M	Contents of applications; technical information COL, OL, & ML not referencing advance reactor design certification to perform design quality testing.	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.48	Standards for review of applications	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.54	Issuance of standard design certification Addition of access requirement	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.55	Duration of certification	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.57	Application for renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.59	Criteria for renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.61	Duration of renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.63(a)(1), 52.63(a)(2), and 52.63(a)(4)	Finality of standard design certifications Amend 52.63(a)(1)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Subpart C - Combined Licenses			
52.73(b)	Relationship to other subparts	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	Contents of Application Training and qualification of power plant personnel Deleted and moved to 10 CFR 50.120	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.79(a)(1)(ii)	<p>Contents of application; technical information</p> <p>A COL not referencing ESP, to include in FSAR statement to ensure design falls within site characteristics envelope</p>	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.79(a)(3)	A COL not referencing ESP to state that terms and conditions of ESP are met	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.79(b)	A COL referencing certified design to demonstrate compliance with 52.47(a)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	A COL not referencing certified design to demonstrate compliance with 52.47(a)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	A COL referencing certified design to submit plant specific PRA and update site specific design information	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
-	A COL not referencing DC to submit plant specific PRA	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.79(d)	A COL application to include emergency plan in FSAR	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
-	To include all other applicable requirements of 50.34	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.79(d)(1)	Updating of emergency preparedness Updating requirement for referencing an ESP	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.81	Standards for review of applications	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.83	<p>Applicability of part 50 provisions</p> <p>Deleted applicability of part 50 provision</p> <p>Moved duration of COL to 52.104</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
	<p>Finality of referenced NRC approvals</p>	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
52.85	Administrative review of applications; hearings	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
52.87	Referral to the ACRS	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
52.89	Environmental review	NRC	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.91	Authorization to conduct site activities	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.97	Issuance of combined licenses Modified 52.97(c) and 52.97(d) for consistency and added 52.97(e) for clarification of applicability of change processes	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.98	Finality of combined license; information requests	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.99	Inspection during construction	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.103	Operation under a COL Modify 52.103(g)	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.104	Duration of combined license	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.105	Transfer of combined license	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.107	Application for renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.109	Continuation of combined license	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

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Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.110	Termination of license	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Subpart D - RESERVED			
Subpart E - Standard Design Approvals			
52.131	Scope of subpart	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.133	Relationship to other subparts	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.135	Filing of applications	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.136	Contents of applications; general information	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.137	Contents of applications; technical information	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.139	Standards for review of applications	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.141	Referral to the ACRS	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.143	Staff approval of design	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.145	Finality of the design approval	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.147	Duration of design approval	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Subpart F - Manufacturing Licenses			
52.151	Scope of subpart	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.153	Relationship to other subparts	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.155	Filing of applications	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.156	Contents of applications; general information	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.157	Contents of applications; technical information in FSAR	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.158	Contents of applications; additional technical information	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.159	Standards for review of applications	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.163	Administrative review of applications; hearings	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.165	Referral to the ACRS	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.167	Issuance of manufacturing license	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.171	Finality of the manufacturing license; information requests	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.173	Duration of manufacturing license	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.175	Transfer of manufacturing license	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.177	Application for renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
52.179	Criteria for renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.181	Duration of renewal	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Appendix Q	Moved the licensing processes of appendix Q to subpart D, Sections 52.111 thru 115, 117, 118, 121, and 123 thru 129	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Subpart E	Standard Design Approvals		
Appendix O	Moved processes of appendix O to Subpart E Remove FDA as a prerequisite for design certification. Added Sections 52.122 and 52.139	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
Subpart F - Manufacturing Licenses			
Appendix M	<p>Moved processes of appendix M to subpart f</p> <p>Remove FDA as a prerequisite for design certification</p> <p>Added Sections 52.122 and 52.139</p>	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission
Subpart H - Enforcement			
52.201	Violations	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
52.203	Criminal penalties	NRC	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
Appendices A, B, & C	<p>Design certifications for ABWR, System 80+, and AP600</p> <p>Change reporting requirements from quarterly to semiannually</p> <p>Revise change control procedures analogous to 50.59</p>		<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
10 CFR Part 54	Requirements for renewal of operating license for nuclear power plants	NRC FOR ALL SECTIONS	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
10 CFR Part 55	Operators license	NRC FOR ALL SECTIONS	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>
10 CFR Part 72	Licensing requirements for independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than class C waste	NRC FOR ALL SECTIONS	<p>The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.</p>

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10 CFR Part 73	Physical protection of plants and materials	NRC FOR ALL SECTIONS	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
10 CFR Part 75	Safeguards on nuclear material— implementation of US/IAEA agreement	NRC FOR ALL SECTIONS	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
10 CFR Part 95	Facility Security clearance and safeguarding of national security information and restricted data	NRC FOR ALL SECTIONS	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
10 CFR Part 140	Financial protection requirements and indemnity agreements	NRC FOR ALL SECTIONS	The State's provisions should not address areas reserved to the NRC pursuant to the Atomic Energy Act, as amended, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Final Rulemaking

Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10 CFR Part 170	Fees for facilities, materials, import and export licenses, and other regulatory services under the Atomic Energy Act of 1954, as amended	[D]	Agreement States may adopt similar provisions as a part of their regulatory programs.

IX. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this rule, the NRC is revising the procedural requirements for early site permits, standard design approvals, standard design certifications, combined licenses, and manufacturing licenses to make certain corrections and changes based on the experience of the previous design certification reviews and on discussions with stakeholders on these licensing processes. These procedural requirements for rulemaking do not establish standards or substantive requirements with which all applicants and licensees must comply. In addition, portions of this rulemaking make conforming changes to regulatory requirements throughout 10 CFR Chapter 1, such as access to national security information and the procedures governing the conduct of hearings in proceedings. These changes also do not establish standards or substantive requirements with which all applicants and licensees must comply. Finally, portions of this rulemaking make conforming changes to technical requirements throughout 10 CFR Chapter 1, in order to make clear their applicability to applicants and licensees under part 52. Inasmuch as the purpose of this rulemaking was not to establish or fundamentally alter these technical requirements, the Commission considers it impractical to perform a reassessment of the fundamental nature of these technical requirements in this rulemaking. In addition, this rule amends certain portions of the three design certification regulations in 10 CFR part 52, appendices A, B, and C (for U.S. ABWR, System 80+, and AP600 designs, respectively). Design certifications are not generic rulemakings in the sense that design certifications do not establish standards or requirements with which all applicants and licensees must comply. Rather, design certifications are

Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certification rulemakings are initiated by an applicant for a design certification, rather than the NRC. For these reasons, the Commission concludes that this action does not constitute the establishment of a standard that contains generally applicable requirements.

X. Environmental Impact - Categorical Exclusion.

The NRC has determined that these amendments fall within the types of actions described as categorical exclusions 10 CFR 51.22(c)(1), (c)(2), and (c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.¹⁶

XI. Paperwork Reduction Act Statement.

This final rule contains new or amended information collection requirements contained in 10 CFR parts 21, 25, 50, 52, and 54 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval numbers 3150-0035, 3150-0046, 3150-0011, 3150-0151, 3150-0155. The changes to 10 CFR parts 19, 20, 26, 51, 55, 72, 73, 75, 95, and 140 do not contain new or amended information collection requirements. Existing requirements were approved by the

¹⁶When 10 CFR part 52 was issued in 1989, the NRC determined that the regulation met the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(3). As stated in the *Federal Register* notice for the final rule (54 FR 15384; April 18, 1989), "It makes no substantive difference for the purpose of the categorical exclusion that the amendments are in a new 10 CFR part 52 rather than in 10 CFR part 50. The amendments are, in fact, amendments to the 10 CFR part 50 procedures and could have been placed in that part." The categorical exclusion for the current proposed change to 10 CFR part 52 is consistent with the original categorical exclusion determination. To ensure that future changes in part 52 are categorically excluded, this rule contains an appropriate change to § 51.22(c)(3).

Office of Management and Budget, approval numbers 3150-0044, 3150-0014, 3150-0146, 3150-0021, 3150-0018, 3150-0132, 3150-0002, 3150-0055, 3150-0047, and 3150-0039.

The burden to the public for the information collections in 10 CFR part 52 is estimated to average **[number to be included before publication, after OMB clearance package is finalized]** hours per response. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden to the records and FOIA/Privacy Services Branch (T-5 F53, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0035, 3150-0046, 3150-0011, 3150-0151, and 3150-0155 with revised information collection requirements), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XII. Regulatory Analysis.

The Commission has prepared a regulatory analysis on this final rule. Consistent with the Regulatory Analysis Guidelines, the NRC performed an aggregate analysis of the

rule. The analysis is based on the assumption that the NRC will receive 19 COL applications during the next 3 years and 1 COL application per year over the next 17 years. The net present value of the part 52 rule modifications are estimated to result in savings to the industry of \$27.0 M, and \$27.0 M using a 3-percent and a 7-percent discount rate, respectively. The provisions of the rule relating to part 21 are estimated to result in net present value cost of \$2.5 M and \$1.9 M to the industry, using a 3-percent and a 7-percent discount rate, respectively. The net present value of the entire rule is estimated to result in a net savings to the industry of \$24.5 M and \$25.1 M at a 3-percent and a 7-percent discount rate, respectively. In addition, the rule is estimated to be a one time net present value savings to the NRC of \$8.4 M.

XIII. Regulatory Flexibility Certification.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects only the licensing of nuclear power plants. The companies that will apply for an approval, certification, permit, site report, or license in accordance with the regulations affected by this rule do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XIV. Backfit Analysis.

The NRC has determined that the backfit rule does not apply to this rule and, therefore, a backfit analysis is not required, because the rule does not contain any provisions that would impose backfitting as defined in the backfit rule, 10 CFR 50.109.

There are no current holders of early site permits, combined licenses, or manufacturing licenses that are protected by the backfitting restrictions in §§ 50.109, 52.39, 52.98, or 52.171. To the extent that this rule revises the requirements for future early site permits, standard design certifications, combined licenses, standard design approvals and manufacturing licenses for nuclear power plants, these revisions do not constitute backfits because they are prospective in nature and the backfit rule is not intended to apply to every NRC action which substantially changes the expectations of future applicants.

Other provisions in this rule would apply to currently-approved standard design approvals and certifications, but they are not protected by the backfitting restrictions in 50.104 or 52.63 because they are either corrections, administrative changes, or provide additional flexibility to applicants or licensees who might reference the design approvals or certifications, and thus constitute a voluntary alternative or relaxation.

Finally, some of the provisions in this rule represent conforming changes throughout 10 CFR Chapter 1 which are being made to reflect Commission adoption of design approvals and design certification processes which should have been made at the time the Commission first adopted these processes by rulemaking. While these conforming changes may, in some cases, affect the way in which a current design certification or design approval may be referenced, they do not directly affect the design approval nor are the conforming changes result in an any inconsistency with the finality provisions in the design certifications or in part 52. Accordingly, the Commission believes that these conforming changes with respect to design approvals and design certifications do not raise new backfitting considerations.

XV. Congressional Review Act.

Under the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 1

Organization and functions (Government Agencies).

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 10

Administrative practice and procedure, Classified information, Government employees, Security measures.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and record keeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and record keeping requirements.

10 CFR Part 25

Classified information, Criminal penalties, Investigations, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 26

Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power reactors, Protection of information, Reporting and recordkeeping requirements.

10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Emergency Planning, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and record keeping requirements.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and record keeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR Part 54

Administrative practice and procedure, Age-related degradation, Backfitting, Classified information, Criminal penalties, Environmental protection, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 55

Criminal penalties, Manpower training programs, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and record keeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and record keeping requirements, Security measures.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and record keeping requirements, Security measures.

10 CFR Part 95

Classified information, Criminal penalties, Reporting and recordkeeping requirements Security measures.

10 CFR Part 140

Criminal penalties, Extraordinary nuclear occurrence, Insurance, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Nuclear power plants and reactors.

For the reasons set forth in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52, 54, 55, 72, 73, 75, 95, 140, 170, and 171.

PART 1 — STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. The authority citation for Part 1 continues to read as follows:

AUTHORITY: Secs. 23, 161, 68 Stat. 925, 948, as amended (42 U.S.C. 2033, 2201); sec. 29, Pub. L. 85-256, 71 Stat. 579, Pub. L. 95-209, 91 Stat. 1483 (42 U.S.C. 2039); sec. 191, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); secs. 201, 203, 204, 205, 209, 88 Stat. 1242, 1244, 1245, 1246, 1248, as amended (42 U.S.C. 5841, 5843, 5844, 5845, 5849); 5 U.S.C. 552, 553; Reorganization Plan No. 1 of 1980, 45 FR 40561, June 16, 1980.

2. In § 1.43, paragraph (a)(2) is revised to read as follows:

§ 1.43 Office of Nuclear Reactor Regulation.

* * * * *

(a) * * *

(2) Receipt, possession, and ownership of source, byproduct, and special nuclear material used or produced at facilities licensed under 10 CFR parts 50, 52, and 54;

* * * * *

PART 2 — RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

3. The authority citation for Part 2 continues to read as follows:

AUTHORITY: Secs.161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552; sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97-425, 96 Stat. 2213, as amended (42 U.S.C. 10143(o)), sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 104, 105, 163, 183i, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Sections 2.105 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200--2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948-951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Section 2.205(j) also issued under Pub. L. 101-410, 104 Stat. 90, as amended by Section 3100(s), Pub. L. 104-134, 110 Stat. 1321-373 (28 U.S.C. 2461 note). Subpart C also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332). Section 2.700a also issued under 5 U.S.C. 554. Sections 2.343, 2.346, 2.754, 2.712 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133), and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553, and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154).

Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart M also issued under sec. 184 (42 U.S.C. 2234) and sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart N also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91-550, 84 Stat. 1473 (42 U.S.C. 2135).

4. In § 2.1, paragraphs (c) and (d) are revised and a new paragraph (e) is added to read as follows:

§ 2.1 Scope.

* * * * *

- (c) Imposing civil penalties under Section 234 of the Act;
- (d) Rulemaking under the Act and the Administrative Procedure Act; and
- (e) Standard design approvals under part 52 of this chapter.

5. In § 2.4, the definitions of *contested proceeding*, *license* and *licensee* are revised to read as follows:

§ 2.4 Definitions.

* * * * *

Contested proceeding means –

- (1) A proceeding in which there is a controversy between the NRC staff and the applicant for a license or permit concerning the issuance of the license or permit or any of the terms or conditions thereof;
- (2) A proceeding in which the NRC is imposing a civil penalty or other enforcement action, and the subject of the civil penalty or enforcement action is an applicant for or holder of a license or permit, or is or was an applicant for a standard design certification under part 52 of this chapter; and

(3) A proceeding in which a petition for leave to intervene in opposition to an application for a license or permit has been granted or is pending before the Commission.

* * * * *

License means a license, including an early site permit, construction permit, operating license, combined license, manufacturing license, or renewed license issued by the Commission.

Licensee means a person who is authorized to conduct activities under a license.

* * * * *

6. The heading of Subpart A is revised to read as follows:

**Subpart A - Procedure for Issuance, Amendment, Transfer, or Renewal of a License, and
Standard Design Approval**

7. Section 2.100 is revised to read as follows:

§ 2.100 Scope of subpart.

This subpart prescribes the procedure for issuance of a license; amendment of a license at the request of the licensee; transfer and renewal of a license; and issuance of a standard design approval under subpart E of part 52 of this chapter.

8. In § 2.101, paragraphs (a)(1), (a)(2), the introductory paragraph of (a)(3), paragraph (a)(3)(ii), paragraph (a)(4), paragraph (a)(5), and paragraph (a-1) are revised to read as follows:

§ 2.101 Filing of application.

(a)(1) An application for a permit, license, a license transfer, a license amendment, a license renewal, and standard design approval, shall be filed with the Director of New Reactors or Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as prescribed by the applicable provisions of this chapter. A prospective applicant may confer informally with the NRC staff before filing an application.

(2) Each application for a license for a facility or for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee will be assigned a docket number. However, to allow a determination as to whether an application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license for a production or utilization facility is complete and acceptable for docketing, it will be initially treated as a tendered application. A copy of the tendered application will be available for public inspection at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room. Generally, the determination on acceptability for docketing will be made within a period of 30 days. However, in selected applications, the Commission may decide to determine acceptability based on the technical adequacy of the application as well as its completeness. In these cases, the Commission, under § 2.104(a), will direct that the notice of hearing be issued as soon as practicable after the application has been tendered, and the determination of acceptability will be made generally within a period of 60 days. For docketing and other requirements for applications under part 61 of this chapter, see paragraph (g) of this section.

(3) If the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, determines that a tendered application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license for a production or utilization facility, and/or any environmental report required under subpart A of part 51 of this chapter, or part

thereof as provided in paragraphs (a)(5) or (a-1) of this section are complete and acceptable for docketing, a docket number will be assigned to the application or part thereof, and the applicant will be notified of the determination. With respect to the tendered application and/or environmental report or part thereof that is acceptable for docketing, the applicant will be requested to:

* * * * *

(ii) Serve a copy on the chief executive of the municipality in which the facility or site which is the subject of an early site permit is to be located or, if the facility or site which is the subject of an early site permit is not to be located within a municipality, on the chief executive of the county, and serve a notice of availability of the application or environmental report on the chief executives of the municipalities or counties which have been identified in the application or environmental report as the location of all or part of the alternative sites, containing the following information, as applicable: Docket number of the application, a brief description of the proposed site and facility; the location of the site and facility as primarily proposed and alternatively listed; the name, address, telephone number, and email address (if available) of the applicant's representative who may be contacted for further information; notification that a draft environmental impact statement will be issued by the Commission and will be made available upon request to the Commission; and notification that if a request is received from the appropriate chief executive, the applicant will transmit a copy of the application and environmental report, and any changes to these documents which affect the alternative site location, to the executive who makes the request. In complying with the requirements of this paragraph, the applicant should not make public distribution of those parts of the application subject to § 2.390(d). The applicant shall submit to the Director of New Reactors or the Director of Nuclear Reactor Regulation an affidavit that service of the notice of availability of the

application or environmental report has been completed along with a list of names and addresses of those executives upon whom the notice was served; and

* * * * *

(4) The tendered application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license will be formally docketed upon receipt by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, of the required additional copies. Distribution of the additional copies shall be deemed to be complete as of the time the copies are deposited in the mail or with a carrier prepaid for delivery to the designated addresses. The date of docketing shall be the date when the required copies are received by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate. Within 10 days after docketing, the applicant shall submit to the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, an affidavit that distribution of the additional copies to Federal, State, and local officials has been completed in accordance with the requirements of this chapter and written instructions furnished to the applicant by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate. Amendments to the application and environmental report shall be filed and distributed and an affidavit shall be furnished to the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, in the same manner as for the initial application and environmental report. If it is determined that all or any part of the tendered application and/or environmental report is incomplete and therefore not acceptable for processing, the applicant will be informed of this determination, and the respects in which the document is deficient.

(5) *Two-part application.* An applicant for a construction permit under part 50 of this chapter or a combined license under part 52 of this chapter for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility may submit the information required of applicants by part 50 or part 52 of the chapter in two parts. One part shall be accompanied by the information required by § 50.30(f) of this chapter, or § 52.80(c) of this chapter, as applicable. The other part shall include any information required by § 50.34(a) and, if applicable, § 50.34a of this chapter, or §§ 52.79 and 52.80(a) and (b), as applicable. One part may precede or follow other parts by no longer than 6 months. If it is determined that either of the parts as described above is incomplete and not acceptable for processing, the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days. Whichever part is filed first shall also include the fee required by §§ 50.30(e) and 170.21 of this chapter and the information required by §§ 50.33, 50.34(a)(1) or 52.79(a)(1), as applicable, and § 50.37 of this chapter. The Director Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will accept for docketing an application for a construction permit under part 50 or a combined license under part 52 for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility where one part of the application as described above is complete and conforms to the requirements of part 50 of this chapter. The additional parts will be docketed upon a determination by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, that it is complete.

* * * * *

(a-1) *Early consideration of site suitability issues.* An applicant for a construction permit under part 50 of this chapter or a combined license under part 52 of this chapter for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility, may request that the Commission conduct an early review and hearing and render an early partial decision in accordance with subpart F of this part on issues of site suitability within the purview of the applicable provisions of parts 50, 51, 52, and 100 of this chapter.

(1) *Construction permit.* The applicant for the construction permit may submit the information required of applicants by the provisions of this chapter in three parts:

(i) Part one shall include or be accompanied by any information required by §§ 50.34(a)(1) and 50.30(f) of this chapter which relates to the issue(s) of site suitability for which an early review, hearing, and partial decision are sought, except that information with respect to operation of the facility at the projected initial power level need not be supplied, and shall include the information required by §§ 50.33(a) through (e) and 50.37 of this chapter. The information submitted shall also include:

(A) Proposed findings on the issues of site suitability on which the applicant has requested review and a statement of the bases or the reasons for those findings,

(B) a range of postulated facility design and operation parameters that is sufficient to enable the Commission to perform the requested review of site suitability issues under the applicable provisions of parts 50, 51, and 100, and

(C) information concerning the applicant's site selection process and long-range plans for ultimate development of the site required by § 2.603(b)(1).

(ii) Part two shall include or be accompanied by the remaining information required by §§ 50.30(f), 50.33, and 50.34(a)(1) of this chapter.

(iii) Part three shall include the remaining information required by §§ 50.34a and (in the case of a nuclear power reactor) 50.34(a) of this chapter.

(iv) The information required for part two or part three shall be submitted during the period the partial decision on part one is effective. Submittal of the information required for part three may precede by no more than 6 months or follow by no more than 6 months the submittal of the information required for part two.

(2) *Combined license under part 52.* An applicant for a combined license under part 52 of this chapter may submit the information required of applicants by the provisions of this chapter in three parts:

(i) Part one shall include or be accompanied by any information required by §§ 52.79(a)(1) and 50.30(f) of this chapter which relates to the issue(s) of site suitability for which an early review, hearing, and partial decision are sought, except that information with respect to operation of the facility at the projected initial power level need not be supplied, and shall include the information required by §§ 50.33(a) through (e) and 50.37 of this chapter. The information submitted shall also include:

(A) Proposed findings on the issues of site suitability on which the applicant has requested review and a statement of the bases or the reasons for those findings;

(B) A range of postulated facility design and operation parameters that is sufficient to enable the Commission to perform the requested review of site suitability issues under the applicable provisions of parts 50, 51, 52, and 100; and

(C) Information concerning the applicant's site selection process and long-range plans for ultimate development of the site required by § 2.621(b)(1).

(ii) Part two shall include or be accompanied by the remaining information required by §§ 50.30(f), 50.33, and 52.79(a)(1) of this chapter.

(iii) Part three shall include the remaining information required by §§ 52.79 and 52.80 of this chapter.

(iv) The information required for part two or part three shall be submitted during the period the partial decision on part one is effective. Submittal of the information required for part three may precede by no more than 6 months or follow by no more than 6 months the submittal of the information required for part two.

* * * * *

9. In § 2.102, paragraph (a) is revised to read as follows:

§ 2.102 Administrative review of application.

(a) During review of an application by the NRC staff, an applicant may be required to supply additional information. The staff may request any one party to the proceeding to confer with the staff informally. In the case of a docketed application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license of this chapter, the staff shall establish a schedule for its review of the application, specifying the key intermediate steps from the time of docketing until the completion of its review.

* * * * *

10. In § 2.104, the introductory text of paragraph (a) is revised, current paragraphs (d) and (e) are redesignated as paragraphs (l) and (m), respectively, and revised, new paragraphs (d), (e), and (f) are added, and paragraphs (g) through (k) are added and reserved, and footnote 1 is revised to read as follows:

§ 2.104 Notice of hearing.

(a) In the case of an application on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest, the Secretary will issue a notice of hearing to be published in the *Federal Register* as required by law at least 15 days, and in the case of an application concerning a construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter or a testing facility, at least 30 days, before the date set for hearing in the notice.¹ In addition, in the case of an application for an early site permit, construction permit or combined license for a facility of the type described in § 50.22 of this chapter, or a testing facility, the notice (other than a notice under paragraph (d) of this section) shall be issued as soon as practicable after the application has been docketed; provided, that if the Commission, under § 2.101(a)(2), decides to determine the acceptability of the application based on its technical adequacy as well as completeness, the notice shall be issued as soon as practicable after the application has been tendered. The notice will state:

* * * * *

(d) *Early site permit.* In the case of an application for an early site permit under subpart A of part 52 of this chapter, the notice will, except as the Commission determines otherwise, state, in implementation of paragraph (a)(3) of this section:

(1) If the proceeding is a contested proceeding, the presiding officer will consider the following issues:

(i) Whether applicable standards and requirements of the Act and the Commission's regulations have been met;

¹If the notice of hearing concerning an application for a construction permit, early site permit, or combined license for a facility of the type described in §50.21(b) or §50.22 of this chapter or a testing facility does not specify the time and place of initial hearing, a subsequent notice will be published in the *Federal Register* which will provide at least 30 days notice of the time and place of that hearing. After this notice is given the presiding officer may reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing at least 30 days notice.

(ii) Whether any required notifications to other agencies or bodies have been duly made;

(iii) If the applicant requests authorization to perform the activities under § 52.17(c) of this chapter, whether there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type described in the application from the standpoint of radiological health and safety considerations under the Act and regulations issued by the Commission.

(iv) Whether there is reasonable assurance that the site is in conformity with the provisions of the Act, and the Commission's regulations;

(v) Whether the applicant is technically qualified to engage in any activities authorized;

(vi) Whether the proposed inspections, tests, analyses and acceptance criteria, including any on emergency planning, are necessary and sufficient within the scope of the early site permit to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(vii) Whether issuance of the early site permit will be inimical to the common defense and security or to the health and safety of the public; and

(viii) Whether, in accordance with the requirements of subpart A of part 52 of this chapter and subpart A of part 51 of this chapter, the early site permit should be issued as proposed.

(2) If the proceeding is not a contested proceeding, the presiding officer will determine, without conducting a *de novo* evaluation of the application, whether:

(i) The application and the record of the proceeding contain sufficient information, and the review of the application by the NRC staff has been adequate to support affirmative findings

on paragraphs (d)(1)(i) through (v), and (vii) of this section, and a negative finding on paragraph (d)(1)(vi) of this section; and

(ii) The review conducted under part 51 of this chapter under the National Environmental Policy Act (NEPA) has been adequate.

(3) Regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with subpart A of part 51 of this chapter:

(i) Determine whether the requirements of Section 102(2) (A), (C), and (E) of the NEPA and subpart A of part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determine the appropriate action to be taken; and

(iii) If the applicant requests authorization to perform the activities under § 52.17(c) of this chapter, whether there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type described in the application from the standpoint of radiological health and safety considerations under the Act and regulations issued by the Commission.

(iv) Determine whether the combined license should be issued, denied or appropriately conditioned to protect environmental values.

(e) In the case of an application for an initial combined license under subpart C of part 52 of this chapter which does not reference an early site permit under subpart A of part 52, the notice will, except as the Commission determines otherwise, state, in implementation of paragraph (a)(3) of this section:

(1) If the proceeding is a contested proceeding, then the presiding officer will consider the following issues with respect to contested matters:

(i) Whether applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Whether any required notifications to other agencies or bodies have been duly made;

(iii) Whether there is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations;

(iv) Whether the applicant is technically and financially qualified to engage in the activities authorized;

(v) Whether issuance of the license will not be inimical to the common defense and security or to the health and safety of the public;

(vi) Whether the proposed inspections, tests, analyses, and acceptance criteria, including those applicable to emergency planning, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(vii) Whether any inspections, tests, or analyses have been successfully completed and the acceptance criteria in a referenced early site permit, standard design certification or for a manufactured reactor have been met, but only to the extent that the combined license application represents that those inspections, tests, and analyses have been successfully completed and the acceptance criteria have been met; and

(viii) Whether, in accordance with the requirements of subpart C of part 52 of this chapter and subpart A of part 51 of this chapter, the combined license should be issued as proposed.

(2) If the proceeding is a contested proceeding, then the presiding officer, including the Commission acting in its function as a presiding officer, will, without conducting a *de novo* evaluation of the application, determine the following with respect to uncontested matters which

are comparable to those matters which otherwise are required to be addressed in a construction permit proceeding under paragraph (b) of this section:

(i) Whether the application and the record of the proceeding contain sufficient information, and the review of the application by the NRC staff has been adequate to support affirmative findings on paragraphs (e)(1)(i) through (vii), and (ix) of this section, and a negative finding on paragraph (e)(1)(viii) of this section; and

(ii) Whether the review conducted under part 51 of this chapter under NEPA has been adequate.

(3) If the proceeding is not a contested proceeding, then the presiding officer, including the Commission acting in its function as a presiding officer, will, without conducting a *de novo* evaluation of the application, determine the following with respect to uncontested matters which are comparable to those which are otherwise required to be addressed in a construction permit proceeding under paragraph (b) of this section:

(i) Whether the application and the record of the proceeding contain sufficient information, and the review of the application by the NRC staff has been adequate to support affirmative findings on paragraphs (e)(1)(i) through (vii), and (ix) of this section, and a negative finding on paragraph (e)(1)(viii) of this section; and

(ii) Whether the review conducted under part 51 of this chapter under NEPA has been adequate.

(4) Regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with subpart A of part 51 of this chapter:

(i) Determine whether the requirements of Section 102(2) (A), (C), and (E) of the NEPA and subpart A of part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determine the appropriate action to be taken; and

(iii) Determine whether the combined license should be issued, denied or appropriately conditioned to protect environmental values.

(f) In the case of an application for a combined license under subpart C of part 52 of this chapter which references an early site permit under subpart A of part 52, the notice will, except as the Commission determines otherwise, state, in implementation of paragraph (a)(3) of this section, the matters as described in paragraph (e) of this section, *provided however*, that the notice will further state that the presiding officer's (including the Commission acting in its function as a presiding officer) consideration of issues under paragraph (e)(2) or (e)(3) of this section is limited to issues which are comparable to those otherwise required to be addressed in a construction permit proceeding under paragraph (b) of this section but which have not been addressed and resolved in the proceeding for the referenced early site permit.

(g)-(k) **RESERVED**

(l) In an application for a construction permit or an operating license for a facility on which a hearing is required by the Act or this chapter, the notice of hearing will, unless the Commission determines otherwise, state:

(1) A time of the hearing, which will be as soon as practicable after compliance with Sections 189a of the Act and this part;

(2) The presiding officer for the hearing, who shall be either an administrative law judge or an atomic safety and licensing board established by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel; and

(3) That matters of radiological health and safety and common defense and security, and matters raised under NEPA, will be considered at another hearing if otherwise required or ordered to be held, for which a notice will be published under paragraphs (a) and (b) of this section, unless otherwise authorized by the Commission.

(m)(1) The Secretary will transmit a notice of hearing on an application for a license for a production or utilization facility including an early site permit, combined license (but not for a manufacturing license), for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, for a license under part 61 of this chapter, for a construction authorization for a HLW repository at a geologic repository operations area under parts 60 or 63 of this chapter, for a license to receive and possess high-level radioactive waste at a geologic repository operations area under parts 60 or 63 of this chapter, and for a license under part 72 of this chapter to acquire, receive or possess spent fuel for the purpose of storage in an independent spent fuel storage installation (ISFSI) to the governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be located or conducted within an Indian reservation).

(2) The Secretary will transmit a notice of hearing on an application for a license under part 72 of this chapter to acquire, receive or possess spent fuel, high-level radioactive waste or radioactive material associated with high-level radioactive waste for the purpose of storage in a monitored retrievable storage installation (MRS) to the same persons who received the notice of docketing under § 72.16(e) of this chapter.

11. In § 2.105, the introductory text of paragraphs (a) and (a)(4) are revised, and paragraphs (a)(12), (b)(3), and (a)(13) are added to read as follows:

§ 2.105 Notice of proposed action.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, before acting thereon, publish in the *Federal*

Register, as applicable, either a notice of intended operation under § 52.103(a) of this chapter and a proposed finding that inspections, tests, analysis, and acceptance criteria for a combined license under subpart C of part 52 have been or will be met, or a notice of proposed action with respect to an application for:

* * * * *

(4) An amendment to an operating license, combined license, or manufacturing license for a facility licensed under §§ 50.21(b) or 50.22 of this chapter, or for a testing facility, as follows:

* * * * *

(12) An amendment to an early site permit issued under subpart A of part 52 of this chapter, as follows:

(i) If the early site permit does not provide authority to conduct the activities allowed under § 50.10(e)(1) of this chapter, the amendment will involve no significant hazards consideration, and though the NRC will provide notice of opportunity for a hearing under this section, it may make the amendment immediately effective and grant a hearing thereafter; and

(ii) If the early site permit provides authority to conduct the activities allowed under § 50.10(e)(1) and the Commission determines under §§ 50.58 and 50.91 of this chapter that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing under § 2.106 of this chapter (if a hearing is requested, which will be held after issuance of the amendment).

(b)* * *

(3) For a notice of intended operation under § 52.103(a) of this chapter, the following information:

- (i) The identification of the NRC action as making the finding required under § 52.103(g) of this chapter;
 - (ii) The manner in which the licensee notifications under 10 CFR 52.99(c) which are required to be made available by 10 CFR 52.99(e)(2) may be obtained and examined;
 - (iii) The manner in which copies of the safety analysis may be obtained and examined;
- and
- (iv) Any conditions, limitations, or restrictions to be placed on the license in connection with the finding under § 52.103(g) of this chapter, and the expiration date or circumstances (if any) under which the conditions, limitations or restrictions will no longer apply.

(13) A manufacturing license under subpart F of part 52 of this chapter.

* * * * *

12. In § 2.106, paragraphs (a) and (b) are revised to read as follows:

§ 2.106 Notice of issuance.

(a) The Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the State and local officials specified in § 2.104(e) and publish a document in the *Federal Register* announcing the issuance of:

(1) A license or an amendment of a license for which a notice of proposed action has been previously published;

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter, or a testing facility, whether or not a notice of proposed action has been previously published; and

(3) The finding under § 52.103(g) of this chapter.

(b) The notice of issuance will set forth:

- (1) In the case of a license or amendment:
 - (i) The nature of the license or amendment;
 - (ii) The manner in which copies of the safety analysis, if any, may be obtained and examined; and
 - (iii) A finding that the application for the license or amendment complies with the requirements of the Act and this chapter.
- (2) In the case of a finding under § 52.103(g) of this chapter:
 - (i) The manner in which copies of the safety analysis, if any, may be obtained and examined; and
 - (ii) A finding that the prescribed inspections, tests, and analyses have been performed, the prescribed acceptance criteria have been met, and that the license complies with the requirements of the Act and this chapter.

* * * * *

13. Section 2.109 is revised to read as follows:

§ 2.109 Effect of timely renewal application.

(a) Except for the renewal of an operating license for a nuclear power plant under 10 CFR 50.21(b) or 50.22, an early site permit under subpart A of part 52 of this chapter, a manufacturing license under subpart F of part 52 of this chapter, or a combined license under subpart C of part 52 of this chapter, if at least 30 days before the expiration of an existing license authorizing any activity of a continuing nature, the licensee files an application for a renewal or for a new license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

(b) If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 50.22 files a sufficient application for renewal of either an operating license or a combined license at

least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

(c) If the holder of an early site permit licensed under subpart A of part 52 of this chapter files a sufficient application for renewal under § 52.29 of this chapter at least 12 months before the expiration of the existing early site permit, the existing permit will not be deemed to have expired until the application has been finally determined.

(d) If the licensee of a manufacturing license under subpart F of part 52 of this chapter files a sufficient application for renewal under § 52.177 of this chapter at least 12 months before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

14. Section 2.110 is revised to read as follows:

§ 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

(a)(1) A submittal for a standard design approval under subpart E of part 52 of this chapter shall be subject to §§ 2.101(a) and 2.390 to the same extent as if it were an application for a permit or license.

(2) Except as specifically provided otherwise by the provisions of appendix Q to parts 50 or 52 of this chapter, a submittal for early review of site suitability issues under appendix Q to parts 50 or 52 of this chapter shall be subject to §§ 2.101(a)(2) through (4) to the same extent as if it were an application for a permit or license.

(b) Upon initiation of review by the NRC staff of a submittal for an early review of site suitability issues under appendix Q of parts 50 or 52 of this chapter, or for a standard design approval under subpart E of part 52 of this chapter, the Director of New Reactors or the Director of Nuclear Reactor Regulation shall publish in the *Federal Register* a notice of receipt of the

submittal, inviting comments from interested persons within 60 days of publication or other time as may be specified, for consideration by the NRC staff and ACRS in their review.

(c)(1) Upon completion of review by the NRC staff and the ACRS of a submittal for a standard design approval, the Director of New Reactors or the Director of the Office of Nuclear Reactor Regulation shall publish in the *Federal Register* a determination as to whether or not the design is acceptable, subject to terms and conditions as may be appropriate, and shall make available at the NRC Web site, <http://www.nrc.gov>, a report that analyzes the design.

(2) Upon completion of review by the NRC staff and, if appropriate by the ACRS, of a submittal for early review of site suitability issues, the NRC staff shall prepare a staff site report which shall identify the location of the site, state the site suitability issues reviewed, explain the nature and scope of the review, state the conclusions of the staff regarding the issues reviewed and state the reasons for those conclusions. Upon issuance of an NRC staff site report, the NRC staff shall publish a notice of the availability of the report in the *Federal Register* and shall make the report available at the NRC Web site, <http://www.nrc.gov>. The NRC staff shall also send a copy of the report to the Governor or other appropriate official of the State in which the site is located, and to the chief executive of the municipality in which the site is located or, if the site is not located in a municipality, to the chief executive of the county.

15. Section 2.111 is revised to read as follows:

§ 2.111 Prohibition of sex discrimination.

No person shall on the grounds of sex be excluded from participation in, be denied a license, standard design approval, or petition for rulemaking (including a design certification), be denied the benefits of, or be subjected to discrimination under any program or activity carried on or receiving Federal assistance under the Act or the Energy Reorganization Act of 1974.

16. In § 2.202, paragraph (e) is revised to read as follows:

§ 2.202 Orders.

* * * * *

(e)(1) If the order involves the modification of a part 50 license and is a backfit, the requirements of § 50.109 of this chapter shall be followed, unless the licensee has consented to the action required.

(2) If the order involves the modification of combined license under subpart C of part 52 of this chapter, the requirements of § 52.98 of this chapter shall be followed unless the licensee has consented to the action required.

(3) If the order involves a change to an early site permit under subpart A of part 52 of this chapter, the requirements of § 52.39 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

(4) If the order involves a change to a standard design certification rule referenced by that plant's application, the requirements, if any, in the referenced design certification rule with respect to changes must be followed, or, in the absence of these requirements, the requirements of § 52.63 of this chapter must be followed, unless the applicant or licensee has consented to follow the action required.

(5) If the order involves a change to a standard design approval referenced by that plant's application, the requirements of § 52.145 of this chapter must be followed unless the applicant or licensee has consented to follow the action required.

(6) If the order involves a modification of a manufacturing license under subpart F of part 52, the requirements of § 52.171 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

17. In § 2.339, paragraph (d) is revised to read as follows:

§ 2.339 Expedited decisionmaking procedure.

* * * * *

(d) The provisions of this section do not apply to an initial decision directing the issuance of a limited work authorization under 10 CFR 50.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization, a combined license under subpart C of part 52 of this chapter, or a manufacturing license under subpart F of part 52.

18. Section 2.340 is revised to read as follows:

§ 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits, and licenses.

(a) *Initial decision - production or utilization facility operating license.* In any initial decision in a contested proceeding on an application for an operating license (including an amendment to or renewal of an operating license) for a production or utilization facility, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, any matter designated by the Commission to be decided by the presiding officer (including those matters which a presiding officer must determine as provided in the relevant provisions of § 2.104), and any matter not put into controversy by the parties, but only to the extent that the presiding officer determines that a serious safety, environmental, or common defense and security matter exists, and the Commission approves of an examination of and decision on the matter upon its referral by the presiding officer. Depending on the resolution of those matters, the Commission, the Director of Nuclear Reactor Regulation, or the Director of New Reactors, as appropriate, after making the requisite findings, will issue, deny or appropriately condition the license.

(b) *Initial decision - combined license under 10 CFR part 52.* In any initial decision in a contested proceeding on an application for a combined license (including an amendment to or renewal of a combined license) under subpart C of part 52 of this chapter, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and any matter designated by the Commission to be decided by the presiding officer (including those matters which a presiding officer must determine in an initial combined license proceeding under § 2.104). Depending on the resolution of those matters, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, after making the requisite findings, will issue, deny or appropriately condition the license.

(c) *Initial decision on finding under 10 CFR 52.103 with respect to acceptance criteria in nuclear power reactor combined licenses.* In any initial decision under § 52.103(g) of this chapter with respect to whether acceptance criteria have been or will be met, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and on any matters designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties shall be referred to the Commission for its determination. The Commission may, in its discretion, treat the matter as a request for action under 10 CFR 2.206 and process the matter in accordance with § 52.103(f). Depending on the resolution of those matters, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, will make the finding under 10 CFR 52.103, or appropriately condition that finding.

(d) *Initial decision - manufacturing license under 10 CFR part 52.* In any initial decision in a contested proceeding on an application for a manufactured license (including an amendment to or renewal of a combined license) under subpart C of part 52 of this chapter, the presiding officer shall make findings of fact and conclusions of law on the matters put into

controversy by the parties to the proceeding, and any matter designated by the Commission to be decided by the presiding officer (including those matters which a presiding officer must determine in a manufacturing licensing proceeding under § 2.104). Depending on the resolution of those matters, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, after making the requisite findings, will issue, deny, or appropriately condition the manufacturing license.

(e) *Initial decision - other proceedings not involving production or utilization facilities.* In proceedings not involving production or utilization facilities, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and on any matters designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties must be referred to the Director of Nuclear Material Safety and Safeguards, or the Director of the Office of Federal and State Materials and Environmental Management Programs, as appropriate. Depending on the resolution of those matters, the Director of Nuclear Material Safety and Safeguards or the Director of the Office of Federal and State Materials and Environmental Management Programs, as appropriate, after making the requisite findings, will issue, deny, revoke or appropriately condition the license, or take other action as necessary or appropriate.

(f) *Immediate effectiveness of certain decisions.* An initial decision directing the issuance or amendment of a limited work authorization under 10 CFR 50.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization under part 50 of this chapter, an operating license under part 50 of this chapter, a combined license under subpart C of part 52 of this chapter, a manufacturing license under subpart F of part 52 of this chapter, or a license under 10 CFR part 72 to store spent fuel in an independent spent fuel storage facility (ISFSI) or a monitored retrievable storage installation (MRS), an initial decision directing issuance of a license under part 61 of this chapter, or an

initial decision under 10 CFR 52.103(g) that acceptance criteria in a combined license have been met, is immediately effective upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective.

(g) - (h) [RESERVED]

(i) *Issuance of authorizations, permits, and licenses - production and utilization facilities.*

The Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, shall issue a limited work authorization under 10 CFR 50.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization under part 50 of this chapter, an operating license under part 50 of this chapter, a combined license under subpart C of part 52 of this chapter, or a manufacturing license under subpart F of part 52 of this chapter within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the appropriate Director has made all findings necessary for issuance of the authorization, permit or license, not within the scope of the initial decision of the presiding officer; and

(2) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342, or the filing of a petition under § 2.206.

(j) *Issuance of finding on acceptance criteria under 10 CFR 52.103.* The Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, shall make the finding under 10 CFR 52.103(g) that acceptance criteria in a combined license have been, or will be met, within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the appropriate Director has made the finding under § 52.103(g) that acceptance criteria have been, or will be met, for those acceptance criteria which are not within the scope of the initial decision of the presiding officer; and

(2) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342, or the filing of a petition under § 2.206.

(k) *Issuance of other licenses.* The Commission or the Director of Nuclear Material Safety and Safeguards, or the Director of the Office of Federal and State Materials and Environmental Management Programs, as appropriate, shall issue a license, including a license under 10 CFR part 72 to store spent fuel in either an independent spent fuel storage facility (ISFSI) located away from a reactor site or at a monitored retrievable storage installation (MRS), within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the appropriate Director has made all findings necessary for issuance of the license, not within the scope of the initial decision of the presiding officer; and

(2) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342, or the filing of a petition under § 2.206.

19. In § 2.390, the introductory text of paragraph (a) is revised to read as follows:

§ 2.390 Public inspections, exemptions, requests for withholding.

(a) Subject to the provisions of paragraphs (b), (d), (e), and (f) of this section, final NRC records and documents, including but not limited to correspondence to and from the NRC regarding the issuance, denial, amendment, transfer, renewal, modification, suspension, revocation, or violation of a license, permit, order, or standard design approval, or regarding a rulemaking proceeding subject to this part shall not, in the absence of an NRC determination of a compelling reason for nondisclosure after a balancing of the interests of the person or agency urging nondisclosure and the public interest in disclosure, be exempt from disclosure and will

be made available for inspection and copying at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, except for matters that are:

* * * * *

20. Subpart D is revised to read as follows:

Subpart D—Additional Procedures Applicable to Proceedings for the Issuance of Licenses To Construct and/or Operate Nuclear Power Plants of Identical Design at Multiple Sites

§ 2.400 Scope of subpart.

§ 2.401 Notice of hearing on construction permit or combined license applications pursuant to appendix N of 10 CFR parts 50 or 52.

§ 2.402 Separate hearings on separate issues; consolidation of proceedings.

§ 2.403 Notice of proposed action on applications for operating licenses pursuant to appendix N of 10 CFR part 50.

§ 2.404 Hearings on applications for operating licenses pursuant to appendix N of 10 CFR part 50.

§ 2.405 Initial decisions in consolidated hearings.

§ 2.406 Finality of decisions on separate issues.

§ 2.407 Applicability of other sections.

§ 2.400 Scope of subpart.

This subpart describes procedures applicable to licensing proceedings which involve the consideration in hearings of a number of applications, filed by one or more applicants pursuant

to appendix N of parts 50 or 52 of this chapter, for licenses to construct and/or operate nuclear power reactors of identical design to be located at multiple sites.

§ 2.401 Notice of hearing on construction permit or combined license applications pursuant to appendix N of 10 CFR parts 50 or 52.

(a) In the case of applications pursuant to appendix N of part 50 of this chapter for construction permits for nuclear power reactors of the type described in § 50.22 of this chapter, or applications pursuant to appendix N of part 52 of this chapter for combined licenses, the Secretary will issue notices of hearing pursuant to § 2.104.

(b) The notice of hearing will also state the time and place of the hearings on any separate phase of the proceeding.

§ 2.402 Separate hearings on separate issues; consolidation of proceedings.

(a) In the case of applications under appendix N of part 50 of this chapter for construction permits for nuclear power reactors of a type described in 10 CFR 50.22, or applications pursuant to appendix N of part 52 of this chapter for combined licenses, the Commission or the presiding officer may order separate hearings on particular phases of the proceeding, such as matters related to the acceptability of the design of the reactor, in the context of the site parameters postulated for the design or environmental matters.

(b) If a separate hearing is held on a particular phase of the proceeding, the Commission or presiding officers of each affected proceeding may, under 10 CFR 2.317, consolidate for hearing on that phase two or more proceedings to consider common issues relating to the applications involved in the proceedings, if it finds that this action will be conducive to the proper dispatch of its business and to the ends of justice. In specifying the

place of this consolidated hearing, due regard will be given to the convenience and necessity of the parties, petitioners for leave to intervene, or the attorneys or representatives of such persons, and the public interest.

§ 2.403 Notice of proposed action on applications for operating licenses pursuant to appendix N of 10 CFR part 50.

In the case of applications pursuant to appendix N of part 50 of this chapter for operating licenses for nuclear power reactors, if the Commission has not found that a hearing is in the public interest, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation will, prior to acting thereon, cause to be published in the *Federal Register*, pursuant to § 2.105, a notice of proposed action with respect to each application as soon as practicable after the applications have been docketed.

§ 2.404 Hearings on applications for operating licenses pursuant to appendix N of 10 CFR part 50.

If a request for a hearing and/or petition for leave to intervene is filed within the time prescribed in the notice of proposed action on an application for an operating license pursuant to appendix N of part 50 of this chapter with respect to a specific reactor(s) at a specific site, and the Commission, the Chief Administrative Judge, or a presiding officer has issued a notice of hearing or other appropriate order, then the Commission, the Chief Administrative Judge, or the presiding officer may order separate hearings on particular phases of the proceeding and/or consolidate for hearing two or more proceedings in the manner described in § 2.402.

§ 2.405 Initial decisions in consolidated hearings.

At the conclusion of a hearing held under this subpart, the presiding officer will render a partial initial decision on the common design. The partial initial decision on the common design may be appealed under § 2.341. If the proceedings have also been consolidated with respect to matters other than the common design under § 2.317(b), the presiding officer may issue a consolidated partial initial decision for those proceedings. No construction permit, full-power operating license, or combined license under part 52 of this chapter will be issued until an initial decision has been issued on all phases of the hearing and all issues under the Act and the National Environmental Policy Act of 1969 appropriate to the proceeding have been resolved.

§ 2.406 Finality of decisions on separate issues.

Notwithstanding any other provision of this chapter, in a proceeding conducted pursuant to this subpart and appendices N of parts 50 or 52 of this chapter, no matter which has been reserved for consideration in one phase of the hearing shall be considered at another phase of the hearing except on the basis of significant new information that substantially affects the conclusion(s) reached at the other phase or other good cause.

§ 2.407 Applicability of other sections.

The provisions of subparts A, C, G, L, and N of this part relating to construction permits, operating licenses, and combined licenses apply, respectively, to construction permits, operating licenses, and combined licenses subject to this subpart, except as may be qualified by the provisions of this subpart.

21. Section 2.500 is revised to read as follows:

§ 2.500 Scope of subpart.

This subpart prescribes procedures applicable to licensing proceedings which involve the consideration in separate hearings of an application for a license to manufacture nuclear power reactors under subpart F of part 52 of this chapter.

22. In § 2.501, the section heading, the introductory text of paragraph (a), and the introductory text of paragraph (b) are revised to read as follows:

§ 2.501 Notice of hearing on application under subpart F of 10 CFR part 52 for a license to manufacture nuclear power reactors.

(a) In the case of an application under subpart F of part 52 of this chapter for a license to manufacture nuclear power reactors of the type described in § 50.22 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the *Federal Register* at least 30 days before the date set for hearing in the notice.² The notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

* * * * *

(b) The notice of hearing shall comply with the requirements of § 2.104(f) of this chapter.

* * * * *

§ 2.502 [REMOVED AND RESERVED]

23. Remove and reserve § 2.502.

§ 2.503 [REMOVED AND RESERVED]

²The thirty-day (30) requirement of this paragraph is not applicable to a notice of the time and place of hearing published by the presiding officer after the notice of hearing described in this section has been published.

24. Remove and reserve § 2.503

§ 2.504 [REMOVED AND RESERVED]

25. Remove and reserve § 2.504

26. Subpart F is revised to read as follows:

Subpart F—Additional Procedures Applicable to Early Partial Decisions on Site Suitability Issues in Connection With an Application for a Construction Permit or Combined License for Certain Utilization Facilities

§ 2.600 Scope of subpart.

§ 2.601 Applicability of other sections.

Early Partial Decisions on Site Suitability-Construction Permit

§ 2.602 Filing Fees.

§ 2.603 Acceptance and docketing of application for early review of site suitability issues in a construction permit proceeding.

§ 2.604 Notice of hearing on application for early review of site suitability issues in construction permit proceeding.

§ 2.605 Additional considerations.

§ 2.606 Partial decision on site suitability issues in construction permit proceeding.

Early Partial Decisions on Site Suitability-Combined License under 10 CFR Part 52

§ 2.621 Acceptance and docketing of application for early review of site suitability issues in a combined license proceeding.

§ 2.623 Notice of hearing on application for early review of site suitability issues in combined license proceeding.

§ 2.625 Additional considerations.

§ 2.627 Partial decision on site suitability issues in combined license proceeding.

§ 2.629 Finality of partial decision on site suitability issues in combined license proceeding.

§ 2.600 Scope of subpart.

This subpart prescribes procedures applicable to licensing proceedings which involve an early submittal of site suitability information in accordance with § 2.101(a-1) and (a-2), and a hearing and early partial decision on issues of site suitability, in connection with an application for a permit to construct a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility; or an application for a combined license under part 52 of this chapter for a nuclear power facility.

(a) The procedures in §§ 2.601 through 2.609 apply to all applications under this subpart.

(b) The procedures in §§ 2.611 through 2.619 apply to applications for a permit to construct a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility.

(c) The procedures in §§ 2.621 through 2.629 apply to applications for combined license under part 52 of this chapter for a nuclear power facility.

§ 2.601 Applicability of other sections.

The provisions of subparts A, C, G, L, and N relating to applications for construction permits and combined licenses, and proceedings thereon apply, respectively, to such

applications and proceedings in accordance with this subpart, except as specifically provided otherwise by the provisions of this subpart.

Early Partial Decisions on Site Suitability—Construction Permit

§ 2.602 Filing fees.

Each application which contains a request for early review of site suitability issues under the procedures of this subpart shall be accompanied by any fee required by § 50.30(e) and part 170 of this chapter.

§ 2.603 Acceptance and docketing of application for early review of site suitability issues in a construction permit proceeding.

(a) Each part of an application for a construction permit submitted in accordance with § 2.101(a–1) of this part will be initially treated as a tendered application. If it is determined that any one of the parts as described in § 2.101(a–1) is incomplete and not acceptable for processing, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days.

(b)(1) The Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will accept for docketing part one of an application for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter, or is a testing facility where part one of the application as described in § 2.101(a–1) is complete. Part one of any

application will not be considered complete unless it contains proposed findings as required by § 2.101(a-1)(1)(i) and unless it describes the applicant's site selection process, specifies the extent to which that process involves the consideration of alternative sites, explains the relationship between that process and the application for early review of site suitability issues, and briefly describes the applicant's long-range plans for ultimate development of the site. Upon assignment of a docket number, the procedures in § 2.101(a)(3) and (4) relating to formal docketing and the submission and distribution of additional copies of the application shall be followed.

(2) Additional parts of the application will be docketed upon a determination by the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, that they are complete.

(c) If part one of the application is docketed, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will cause to be published in the *Federal Register* and send to the Governor or other appropriate official of the State in which the site is located, a notice of docketing of the application which states the purpose of the application, states the location of the proposed site, states that a notice of hearing will be published, requests comments within 120 days or such other time as may be specified on the initiation or outcome of an early site review from Federal, State, and local agencies and interested persons, and in the case of applications filed under Section 103 of the Act, states that a person who wishes to have his views on the antitrust aspects of the application presented to the Attorney General for consideration shall submit such views in accordance with a subsequent notice that will be published in the *Federal Register*. In the case of a nuclear power reactor, such subsequent notice will be published following submission of the information required by § 50.33a of this chapter.

§ 2.604 Notice of hearing on application for early review of site suitability issues in construction permit proceeding.

(a) Where an applicant for a construction permit requests an early review and hearing and an early partial decision on issues of site suitability pursuant to § 2.101(a-1), the provisions in the notice of hearing setting forth the matters of fact and law to be considered, as required by § 2.104, shall be modified so as to relate only to the site suitability issue or issues under review.

(b) After docketing of part two of the application, as provided in §§ 2.101(a-1) and 2.603, a supplementary notice of hearing will be published under § 2.104 with respect to the remaining unresolved issues in the proceeding within the scope of § 2.104. This supplementary notice of hearing will provide that any person whose interest may be affected by the proceeding and who desires to participate as a party in the resolution of the remaining issues shall file a petition for leave to intervene pursuant to § 2.309 within the time prescribed in the notice. This supplementary notice will also provide appropriate opportunities for participation by a representative of an interested State under § 2.315(c) and for limited appearances under § 2.315(a).

(c) Any person who was permitted to intervene as a party under the initial notice of hearing on site suitability issues and who was not dismissed or did not withdraw as a party may continue to participate as a party to the proceeding with respect to the remaining unresolved issues, provided that within the time prescribed for filing of petitions for leave to intervene in the supplementary notice of hearing, he or she files a notice of his intent to continue as a party, along with a supporting affidavit identifying the specific aspect or aspects of the subject matter of the proceeding as to which he or she wishes to continue to participate as a party and setting forth with particularity the basis for his contentions with regard to each aspect or aspects. A party who files a non-timely notice of intent to continue as a party may be dismissed from the proceeding, absent a determination that the party has made a substantial showing of good

cause for failure to file on time, and with particular reference to the factors specified in §§ 2.309(c)(1)(i) through (iv) and 2.309(d). The notice will be ruled upon by the Commission or presiding officer designated to rule on petitions for leave to intervene.

(d) To the maximum extent practicable, the membership of any atomic safety and licensing board designated to preside in the proceeding on the remaining unresolved issues pursuant to the supplemental notice of hearing will be the same as the membership designated to preside in the initial notice of hearing on site suitability issues.

§ 2.605 Additional considerations.

(a) The Commission will not conduct more than one review of site suitability issues with regard to a particular site prior to filing and review of part two of the application described in § 2.101(a-1) of this part.

(b) The Commission, upon its own initiative, or upon the motion of any party to the proceeding filed at least 60 days prior to the date of the commencement of the evidentiary hearing on site suitability issues, may decline to initiate an early hearing or render an early partial decision on any issue or issues of site suitability:

(1) In cases where no partial decision on the relative merits of the proposed site and alternative sites under subpart A of part 51 of this chapter is requested, upon determination that there is a reasonable likelihood that further review would identify one or more preferable alternative sites and the partial decision on one or more site suitability issues would lead to an irreversible and irretrievable commitment of resources prior to the submittal of the remainder of the information required by § 50.30(f) of this chapter that would prejudice the later review and decision on such alternative sites; or

(2) In cases where it appears that an early partial decision on any issue or issues of site suitability would not be in the public interest considering:

(i) the degree of likelihood that any early findings on those issues would retain their validity in later reviews;

(ii) the objections, if any, of cognizant State or local government agencies to the conduct of an early review on those issues; and

(iii) the possible effect on the public interest and the parties of having an early, if not necessarily conclusive, resolution of those issues.

§ 2.606 Partial decision on site suitability issues.

(a) The provisions of §§ 2.331, 2.339, 2.340(g), 2.343, 2.712, and 2.713 shall apply to any partial initial decision rendered in accordance with this subpart. A limited work authorization may not be issued under 10 CFR 50.10(e) and no construction permit may be issued without completion of the full review required by Section 102(2) of the National Environmental Policy Act of 1969, as amended, and subpart A of part 51 of this chapter. The authority of the Commission to review such a partial initial decision *sua sponte*, or to raise *sua sponte* an issue that has not been raised by the parties, will be exercised within the same time period as in the case of a full decision relating to the issuance of a construction permit.

(b)(1) A partial decision on one or more site suitability issues pursuant to the applicable provisions of part 50, subpart A of part 51, and part 100 of this chapter issued in accordance with this subpart shall:

(i) clearly identify the site to which the partial decision applies; and

(ii) indicate to what extent additional information may be needed and additional review may be required to enable the Commission to determine in accordance with the provisions of the Act and the applicable provisions of the regulations in this chapter whether a construction permit for a facility to be located on the site identified in the partial decision should be issued or denied.

(2) Following either the Commission (acting in the function of a presiding officer) issuance of a partial initial decision, or completion of Commission review of the partial initial decision of the Atomic Safety and Licensing Board, after hearing, on the site suitability issues, the partial decision shall remain in effect either for a period of 5 years or, where the applicant for the construction permit has made timely submittal of the information required to support the application as provided in § 2.101(a–1), until the proceeding for a permit to construct a facility on the site identified in the partial decision has been concluded,³ unless the Commission or Atomic Safety and Licensing Board, upon its own initiative or upon motion by a party to the proceeding, finds that there exists significant new information that substantially affects the earlier conclusions and reopens the hearing record on site suitability issues. Upon good cause shown, the Commission may extend the 5-year period during which a partial decision shall remain in effect for a reasonable period of time not to exceed 1 year.

Early Partial Decisions on Site Suitability—Combined License under 10 CFR Part 52

§ 2.621 Acceptance and docketing of application for early review of site suitability issues in a combined license proceeding.

(a) Each part of an application submitted in accordance with § 2.101(a–1) of this part will be initially treated as a tendered application. If it is determined that any one of the parts as described in § 2.101(a–1) is incomplete and not acceptable for processing, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will inform the applicant of this determination and the respects in which the

³The partial decision on site suitability issues shall be incorporated in the decision regarding issuance of the combined license to the extent that it serves as a basis for the decision on a specific site issue.

document is deficient. Such a determination of completeness will generally be made within a period of 30 days.

(b)(1) The Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will accept for docketing an application for a combined license for a nuclear power facility where part one of the application as described in § 2.101(a-1) is complete. Part one of any application will not be considered complete unless it contains proposed findings as required by § 2.101(a-1)(1)(i) and unless it describes the applicant's site selection process, specifies the extent to which that process involves the consideration of alternative sites, explains the relationship between that process and the application for early review of site suitability issues, and briefly describes the applicant's long-range plans for ultimate development of the site. Upon assignment of a docket number, the procedures in § 2.101(a)(3) and (4) relating to formal docketing and the submission and distribution of additional copies of the application shall be followed.

(2) Additional parts of the application will be docketed upon a determination by the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, that they are complete.

(c) If part one of the application is docketed, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will cause to be published in the *Federal Register* and send to the Governor or other appropriate official of the State in which the site is located, a notice of docketing of the application which states the purpose of the application, states the location of the proposed site, states that a notice of hearing will be published, requests comments within 120 days or such other time as may be specified on the initiation or outcome of an early site review from Federal, State, and local agencies and interested persons.

§ 2.623 Notice of hearing on application for early review of site suitability issues in combined license proceeding.

(a) Where an applicant for a combined license under part 52 of this chapter requests an early review and hearing and an early partial decision on issues of site suitability pursuant to § 2.101(a-2), the provisions in the notice of hearing setting forth the matters of fact and law to be considered, as required by § 2.104, shall be modified so as to relate only to the site suitability issue or issues under review. The notice will provide appropriate opportunities for participation by a representative of an interested State under § 2.315(c) and for limited appearances under § 2.315(a), limited however, to the issues of site suitability for which early review has been requested by the applicant.

(b) After docketing of part two of the application, as provided in §§ 2.101(a-1) and 2.603, a supplementary notice of hearing will be published under § 2.104 with respect to the remaining unresolved issues in the proceeding within the scope of § 2.104. This supplementary notice of hearing will provide that any person whose interest may be affected by the proceeding and who desires to participate as a party in the resolution of the remaining issues shall file a petition for leave to intervene pursuant to § 2.309 within the time prescribed in the notice. This supplementary notice will also provide appropriate opportunities for participation by a representative of an interested State under § 2.315(c) and for limited appearances under § 2.315(a).

(c) Any person who was permitted to intervene as a party under the initial notice of hearing on site suitability issues and who was not dismissed or did not withdraw as a party may continue to participate as a party to the proceeding without having to demonstrate standing under § 2.309(d), *provided, however*, that within the time prescribed for filing of petitions for leave to intervene in the supplementary notice of hearing, the party files a notice of intent to continue as a party. The notice must include the information required by § 2.309(f). A party

who files a non-timely notice of intent to continue as a party may be dismissed from the proceeding, absent a determination that the party has made a substantial showing of good cause for failure to file on time, and with particular reference to the factors specified in §§ 2.309(c)(1)(i) through (iv) and 2.309(d). The notice will be ruled upon by the Commission or presiding officer designated to rule on petitions for leave to intervene.

(d) To the maximum extent practicable, the presiding officer (as applicable, the membership of the licensing board) designated to preside in the proceeding on the remaining unresolved issues pursuant to the supplemental notice of hearing will be the same as the presiding officer (as applicable, the membership of the licensing board) designated to preside in the initial notice of hearing on site suitability issues.

§ 2.625 Additional considerations.

(a) The Commission will not conduct more than one review of site suitability issues with regard to a particular site prior to filing and review of part two of the application described in § 2.101(a-1) of this part.

(b) The Commission, upon its own initiative, or upon the motion of any party to the proceeding filed at least 60 days prior to the date of the commencement of the evidentiary hearing on site suitability issues, may decline to initiate an early hearing or render an early partial decision on any issue or issues of site suitability:

(1) In cases where no partial decision on the relative merits of the proposed site and alternative sites under subpart A of part 51 is requested, upon determination that there is a reasonable likelihood that further review would identify one or more preferable alternative sites and the partial decision on one or more site suitability issues would lead to an irreversible and irretrievable commitment of resources prior to the submittal of the remainder of the information

required by § 50.30(f) of this chapter that would prejudice the later review and decision on such alternative sites; or

(2) In cases where it appears that an early partial decision on any issue or issues of site suitability would not be in the public interest considering:

(i) the degree of likelihood that any early findings on those issues would retain their validity in later reviews;

(ii) the objections, if any, of cognizant State or local government agencies to the conduct of an early review on those issues; and

(iii) the possible effect on the public interest and the parties of having an early, if not necessarily conclusive, resolution of those issues.

§ 2.627 Partial decision on site suitability issues in combined license proceeding.

(a) The provisions of §§ 2.331, 2.339, 2.340(b), 2.343, 2.712, and 2.713 shall apply to any partial initial decision rendered in accordance with this subpart. Section 2.340(c) shall not apply to any partial initial decision rendered in accordance with this subpart. A limited work authorization may not be issued under 10 CFR 50.10(e) and no construction permit may be issued without completion of the full review required by Section 102(2) of the National Environmental Policy Act of 1969, as amended, and subpart A of part 51 of this chapter. The authority of the Commission to review such a partial initial decision sua sponte, or to raise sua sponte an issue that has not been raised by the parties, will be exercised within the same time period as in the case of a full decision relating to the issuance of a construction permit.

(b)(1) A partial decision on one or more site suitability issues pursuant to the applicable provisions of part 50, subpart A of part 51, and part 100 of this chapter issued in accordance with this subpart shall:

(i) clearly identify the site to which the partial decision applies; and

(ii) indicate to what extent additional information may be needed and additional review may be required to enable the Commission to determine in accordance with the provisions of the Act and the applicable provisions of the regulations in this chapter whether a construction permit for a facility to be located on the site identified in the partial decision should be issued or denied.

(2) Following either the Commission (acting in the function of a presiding officer) issuance of a partial initial decision, or completion of Commission review of the partial initial decision of the presiding officer, after hearing, on the site suitability issues, the partial decision shall remain in effect either for a period of 5 years or, where the applicant for the combined license has made timely submittal of the information required to support the application as provided in § 2.101(a-2), until the proceeding for a combined license on the site identified in the partial decision has been concluded, unless the Commission or presiding officer, upon its own initiative or upon motion by a party to the proceeding, finds that there exists significant new information that substantially affects the earlier conclusions and reopens the hearing record on site suitability issues. Upon good cause shown, the Commission may extend the 5-year period during which a partial decision shall remain in effect for a reasonable period of time not to exceed 1 year.

§ 2.629 Finality of partial decision on site suitability issues in combined license proceeding.

(a) The partial decision on site suitability issues in combined license proceeding shall be incorporated in the decision regarding issuance of a combined license. Except as provided in 10 CFR 2.758, in making the findings required for issuance of a combined license, the Commission shall treat as resolved those matters resolved in connection with the issuance of the partial decision on site suitability issues. If the Commission reaches an adverse decision,

the application shall be denied without prejudice for resubmission, *provided, however*, that in determining whether the resubmitted application is complete and acceptable for docketing under § 2.101(a)(3), the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, shall determine whether the resubmitted application addresses those matters identified as bases for denial of the original application.

(b) Notwithstanding any provision in 10 CFR 50.109, while a partial decision on site suitability is in effect under § 2.617(b)(2), the Commission may not modify, rescind, or impose new requirements with respect to matters within the scope of the site suitability decision, whether on its own motion, or in response to a request or petition from any person, unless the Commission determines that a modification to the original decision is necessary either for compliance with the Commission's regulations applicable and in effect at the time the partial decision was issued, or to assure adequate protection of the public health and safety or the common defense and security.

27. Section 2.800 is revised to read as follows:

§ 2.800 Scope and applicability.

(a) This subpart governs the issuance, amendment, and repeal of regulations in which participation by interested persons is prescribed under Section 553 of title 5 of the U.S. Code.

(b) The procedures in §§ 2.804 through 2.810 apply to all rulemakings.

(c) The procedures in §§ 2.802 through 2.803 apply to all petitions for rulemaking except for initial applications for standard design certification rulemaking under subpart B of part 52 of this chapter, and subsequent petitions for amendment of an existing design certification rule filed by the original applicant for the design certification rule.

(d) The procedures in §§ 2.811 through 2.819, as supplemented by the provisions of subpart B of part 52, apply to standard design certification rulemaking.

28. Section 2.801 is revised to read as follows:

§ 2.801 Initiation of rulemaking.

Rulemaking may be initiated by the Commission at its own instance, on the recommendation of another agency of the United States, or on the petition of any other interested person, including an application for design certification under subpart B of part 52 of this chapter.

29. In subpart H, §§ 2.811, 2.813, 2.815, 2.817 and 2.819 are added to read as follows:

§ 2.811 Filing of standard design certification application; required copies.

(a) *Serving of applications.* The signed original of an application for a standard design certification, including all amendments to the applications must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by facsimile; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail at EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent.

(b) *Form of application.* Each original of an application and an amendment of an application must meet the requirements in § 2.813.

(c) *Capability to provide additional copies.* The applicant shall maintain the capability to generate additional copies of the general information and the safety analysis report, or part thereof or amendment thereto, for subsequent distribution in accordance with the written instructions of the Director, Office of New Reactors, the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate.

(d) *Public hearing copy.* In any hearing conducted under subpart O of this part for a design certification rulemaking, the applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding, and shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements of this part.

(e) *Pre-application consultation.* A prospective applicant for a standard design certification may consult with the NRC before filing an application by writing to the Chief, New Reactor Licensing Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with respect to the subject matters listed in § 2.802(a)(1)(i) through (iii) of this chapter. A prospective petitioner also may telephone the Rulemaking, Directives, and Editing Branch on (301) 415-7163, or toll free on (800) 368-5642, or send e-mail to NRCREP@nrc.gov on these subject matters. In addition, a prospective applicant may confer informally with the NRC staff BEFORE filing an application for a standard design certification, and the limitations in § 2.802(a)(2) do not apply.

§ 2.813 Written communications.

(a) *General requirements.* All correspondence, reports, and other written communications from the applicant to the Nuclear Regulatory Commission concerning the

regulations in this subpart, and parts 50, 52, and 100 of this chapter must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail at EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(b) *Form of communications.* All paper copies submitted to meet the requirements set forth in paragraph (a) of this section must be typewritten, printed or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements imposed on paper submissions may be granted for the submission of micrographic, photographic, or similar forms.

(c) *Regulation governing submission.* An applicant submitting correspondence, reports, and other written communications under the regulations of this chapter is requested but not required to cite whenever practical, in the upper right corner of the first page of the submission, the specific regulation or other basis requiring submission.

§ 2.815 Docketing and acceptance review.

(a) Each application for a standard design certification will be assigned a docket number. However, to allow a determination as to whether an application is complete and acceptable for docketing, it will be initially treated as a tendered application. A copy of the tendered application will be available for public inspection at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room. Generally, the determination on acceptability for docketing will be made within a period of 30 days. The Commission may decide to determine acceptability on the basis of the technical adequacy of the application as well as its completeness.

(b) If the Commission determines that a tendered application is complete and acceptable for docketing, a docket number will be assigned to the application or part thereof, and the applicant will be notified of the determination.

§ 2.817 Withdrawal of application.

(a) The Commission may permit an applicant to withdraw an application for a standard design certification before the issuance of a notice of proposed rulemaking on such terms and conditions as the Commission may prescribe, or may, on receiving a request for withdrawal of an application, deny the application or dismiss it without prejudice. The NRC will publish in the *Federal Register* a document withdrawing the application, if the notice of receipt of the application, an advance notice of proposed rulemaking, or a notice of proposed rulemaking for the standard design certification has been previously published in the *Federal Register*. If the notice of receipt, advance notice of proposed rulemaking or notice of proposed rulemaking was published on the NRC Web site, then the notice of action on the withdrawal will also be published on the NRC Web site.

(b) The withdrawal of an application does not authorize the removal of any document from the files of the Commission.

§ 2.819 Denial of application for failure to supply information.

(a) The Commission may deny an application for a standard design certification if an applicant fails to respond to a request for additional information within 30 days from the date of the request, or within such other time as may be specified.

(b) If the Commission denies an application because the applicant has failed to respond in a timely fashion to a request for additional information, the NRC will publish in the *Federal Register* a notice of denial and will notify the applicant with a simple statement of the grounds of denial. If a notice of receipt of application, advance notice of proposed rulemaking, or notice of proposed rulemaking for a standard design certification was published on the NRC Web site, then the notice of action on the denial will also be published on the NRC Web site.

30. In § 2.1202, paragraph (a) is revised to read as follows:

§ 2.1202 Authority and role of NRC staff.

(a) During the pendency of any hearing under this subpart, consistent with the NRC staff's findings in its review of the application or matter which is the subject of the hearing and as authorized by law, the NRC staff is expected to issue its approval or denial of the application promptly, or take other appropriate action on the underlying regulatory matter for which a hearing was provided. When the NRC staff takes its action, it shall notify the presiding officer and the parties to the proceeding of its action. That notice must include the NRC staff's position on the matters in controversy before the presiding officer with respect to the staff action. The NRC staff's action on the matter is effective upon issuance by the staff, except in matters involving:

(1) An application to construct and/or operate a production or utilization facility (including an application for a limited work authorization under 10 CFR 50.12, or an application for a combined license under subpart C of 10 CFR part 52);

- (2) An application for an early site permit under subpart A of 10 CFR part 52;
- (3) An application for a manufacturing license under subpart F of 10 CFR part 52;
- (4) An application for an amendment to a construction authorization for a high-level radioactive waste repository at a geologic repository operations area falling under either 10 CFR 60.32(c)(1) or 10 CFR part 63; and
- (5) Production or utilization facility licensing actions that involve significant hazards considerations as defined in 10 CFR 50.92.

* * * * *

§ 2.1211 [Removed]

31. Section 2.1211 is removed.

PART 10 - CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION OR AN EMPLOYMENT CLEARANCE

32. The authority citation for Part 10 continues to read as follows:

AUTHORITY: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O. 10450, 3 CFR parts 1949-1953 COMP., p. 936, as amended; E.O. 10865, 3 CFR 1959-1963 COMP., p. 398, as amended; 3 CFR Table 4; E.O. 12968, 3 CFR 1995 COM., p. 396.

33. In § 10.1, paragraphs (a)(1) and (a)(2) are revised and paragraph (a)(3) is added to read as follows:

§ 10.1 Purpose.

(a)* * *

(1) The eligibility of individuals who are employed by or applicants for employment with NRC contractors, agents, and other individuals who are NRC employees or applicants for NRC employment, and other persons designated by the Deputy Executive Director for Information Services and Administration and Chief Information Officer of the NRC, for access to Restricted Data under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, or for access to national security information;

(2) The eligibility of NRC employees, or the eligibility of applicants for employment with the NRC, for employment clearance; and

(3) The eligibility of individuals who are employed by or are applicants for employment with NRC licensees, certificate holders, holders of standard design approvals under part 52 of this chapter, applicants for licenses, certificates, and NRC approvals, and others who may require access related to a license, certificate, or NRC approval, or other activities as the Commission may determine, for access to Restricted Data under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, or for access to national security information.

* * * * *

34. In § 10.2, paragraph (b) is revised to read as follows:

§ 10.2 Scope.

* * * * *

(b) NRC licensees, certificate holders and holders of standard design approvals under part 52 of this chapter, applicants for licenses, certificates, and standard design approvals under part 52 of this chapter, and their employees (including consultants) and applicants for employment (including consulting);

PART 19 - NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS;

INSPECTION AND INVESTIGATIONS

35. The authority citation for Part 19 is revised to read as follows:

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282, 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 19.32 is also issued under sec. 401, 88 Stat. 1254 (42 U.S.C. 2000d, 42 U.S.C. 5891).

36. Section 19.1 is revised to read as follows:

§ 19.1 Purpose.

The regulations in this part establish requirements for notices, instructions, and reports by licensees and regulated entities to individuals participating in NRC-licensed and regulated activities and options available to these individuals in connection with Commission inspections of licensees and regulated entities, and to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, titles II and IV of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder. The regulations in this part also establish the rights and responsibilities of the Commission and individuals during interviews compelled by subpoena as part of agency inspections or investigations under Section 161c of

the Atomic Energy Act of 1954, as amended, on any matter within the Commission's jurisdiction.

37. Section 19.2 is revised to read as follows:

§ 19.2 Scope.

(a) The regulations in this part apply to:

(1) All persons who receive, possess, use, or transfer material licensed by the NRC under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility under parts 50 or 52 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) under part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter;

(2) All applicants for and holders of licenses (including construction permits and early site permits) under parts 50, 52, and 54 of this chapter;

(3) All applicants for and holders of a standard design approval under subpart E of part 52; and

(4) All applicants for a standard design certification under subpart B of part 52 of this chapter, and those (former) applicants whose designs have been certified under that subpart.

(b) The regulations in this part regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the NRC other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued under 10 CFR 2.702.

38. In § 19.3 the definitions of *License* and *Worker* are revised, and the definitions of *Regulated entities* and *Regulated activities* are added to read as follows:

§ 19.3 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to manufacture, construct and/or operate a production or utilization facility under parts 50, 52, or 54 of this chapter.

* * * * *

Regulated activities means any activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or any title of the Energy Reorganization Act of 1972, as amended.

Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an applicant for or holder of a standard design approval under subpart E of part 52 of this chapter or a standard design certification under subpart B of part 52 of this chapter.

* * * * *

Worker means an individual engaged in activities licensed or regulated by the Commission and controlled by a licensee or regulated entity, but does not include the licensee or regulated entity.

39. In § 19.11, paragraph (c) is removed and reserved, and the introductory text of paragraph (a), and paragraphs (b), (d), and (e) are revised, and paragraphs (f) and (g) are added to read as follows:

§ 19.11 Posting of notices to workers.

(a) Each licensee (except for a holder of an early site permit under subpart A of part 52 of this chapter, or a holder of a manufacturing license under subpart F of part 52 of this chapter) shall post current copies of the following documents:

* * * * *

(b) Each applicant for and holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, each applicant for a standard design certification under subpart B of part 52 of this chapter, and each applicant for and holder of a manufacturing license under subpart F of part 52 of this chapter shall post:

(1) The regulations in this part;

(2) The operating procedures applicable to the activities regulated by the NRC which are being conducted by the applicant or holder; and

(3) Any notice of violation, proposed imposition of civil penalty, or order issued under subpart B of part 2 of this chapter, and any response from the applicant or holder.

(c) **[Reserved]**

(d) If posting of a document specified in paragraphs (a)(1), (2) or (3), or (b)(1) or (2) of this section is not practicable, the licensee or regulated entity may post a notice which describes the document and states where it may be examined.

(e)(1) Each licensee, each applicant for a specific license, each applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, and each applicant for a standard design certification under subpart B of part 52 of this chapter shall prominently post NRC Form 3, "Notice to Employees," dated August 1997. Later versions of NRC Form 3 that supersede the August 1997 version shall replace the previously posted version within 30 days of receiving the revised NRC Form 3 from the Commission.

(2) Additional copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-6157, via e-mail to forms@nrc.gov, or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the home page.

(f) Documents, notices, or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in NRC-licensed or regulated activities to observe them on the way to or from any particular licensed or regulated activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(g) Commission documents posted under paragraphs (a)(4) or (b)(3) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's or regulated entity's response, if any, shall be posted within 2 working days after dispatch by the licensee or regulated entity. These documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

40. Section 19.14 is revised to read as follows:

§ 19.14 Presence of representatives of licensees and regulated entities, and workers during inspections.

(a) Each licensee, applicant for a license, applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, applicant for an early site permit under subpart A of part 52 of this chapter, and applicant for a standard design certification under subpart B of part 52 of this chapter shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records under the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee, regulated entity, or the licensee's or regulated entity's representative may accompany Commission inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee or regulated entity shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in NRC-licensed or regulated activities under control of the licensee or regulated entity, and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees or regulated entities, and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee or regulated entity, and the workers' representative an individual who is not routinely engaged in licensed or regulated activities under control of the licensee or regulated entity (for example, a consultant to the licensee, the regulated entity, or the workers' representative), shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Commission inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that

area shall be an individual previously authorized by the licensee or regulated entity to enter that area.

41. Section 19.20 is revised to read as follows:

§ 19.20 Employee protection.

Employment discrimination by a licensee, a holder of a certificate of compliance issued under part 76 of this chapter or regulated entity subject to the requirements in this part as delineated in § 19.2(a), or a contractor or subcontractor of a licensee, a holder of a certificate of compliance issued under part 76 of this chapter, or regulated entity subject to the requirements in this part as delineated in § 19.2(a), against an employee for engaging in protected activities under this part or parts 30, 40, 50, 52, 54, 60, 61, 63, 70, 72, 76, or 150 of this chapter is prohibited.

42. Section 19.31 is revised to read as follows:

§ 19.31 Application for exemptions.

The Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law, will not result in undue hazard to life and property.

43. Section 19.32 is revised to read as follows:

§ 19.32 Discrimination prohibited.

No person shall on the grounds of sex be excluded from participation in, be denied a license, be denied the benefit of, or be subjected to discrimination under any program or activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as

amended, or under any title of the Energy Reorganization Act of 1974, as amended. This provision will be enforced through agency provisions and regulations similar to those already established, with respect to racial and other discrimination, under Title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

44. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

45. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 52, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under § 35.75, or to exposure from voluntary participation in medical research programs.

46. In § 20.1401 paragraph (a) is revised to read as follows:

§ 20.1401 General provisions and scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, and 72 of this chapter, and release of part of a facility or site for unrestricted use in accordance with § 50.83 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. For high-level and low-level waste disposal facilities (10 CFR parts 60, 61, and 63), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to appendix A to 10 CFR part 40 or the uranium solution extraction facilities.

* * * * *

47. Section 20.1406 is revised to read as follows:

§ 20.1406 Minimization of contamination.

(a) Applicants for licenses, other than early site permits and manufacturing licenses under part 52 of this chapter and renewals, whose applications are submitted after August 20, 1997, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) Applicants for standard design certifications, standard design approvals, and manufacturing licenses under part 52 of this chapter, whose applications are submitted after August 20, 1997, shall describe in the application how facility design will minimize, to the extent

practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

48. In § 20.2203, paragraphs (c) and (d) are revised to read as follows:

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

* * * * *

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

(d) All licensees, other than those holding an operating license or a combined license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing either by mail addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail to EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission,

Washington, DC 20555-0001. A copy should be sent to the appropriate NRC Regional Office listed in appendix D to this part.

PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

49. The authority citation for Part 21 continues to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C. 2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended 1246 (42 U.S.C. 5841, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

50. In § 21.2, paragraphs (a), (b), and (c) are revised to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to:

(1) Each individual, partnership, corporation, or other entity applying for or holding a license or permit under the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and each director and responsible officer of such a licensee;

(2) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, that constructs

a production or utilization facility licensed for manufacture, construction, or operation under parts 50 or 52 of this chapter, an ISFSI for the storage of spent fuel licensed under part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or part 72 of this chapter;

(3) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule under part 52 of this chapter; or supplying basic components with respect to that design certification, and each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, whose application for design certification has been granted under part 52 of this chapter, or who has supplied or is supplying basic components with respect to that design certification;

(4) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for or holding a standard design approval under part 52 of this chapter; or supplying basic components with respect to a standard design approval under part 52 of this chapter;

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 of this chapter or a combined license under part 52 of this chapter (for the period of construction until the date that the Commission makes the finding under § 52.103(g) of this chapter), or to manufacture a facility under part 52 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and

responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50 or part 52 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

* * * * *

51. In § 21.3 the definitions of *basic component*, *defect*, *deviation*, and *substantial safety hazard* are revised to read as follows:

§ 21.3 Definitions.

* * * * *

Basic component. (1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

- (A) The integrity of the reactor coolant pressure boundary;
- (B) The capability to shut down the reactor and maintain it in a safe-shutdown condition;

or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

(2) When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

(i) The integrity of the reactor coolant pressure boundary;

(ii) The capability to shut down the reactor and maintain it in a safe-shutdown condition;

or

(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

* * * * *

Defect means:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard;

(2) The installation, use, or operation of a basic component containing a defect as defined in this section;

(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter; or

(5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

Deviation means a departure from the technical requirements included in a procurement document, or specified in early site permit information, a design certification or standard design approval.

* * * * *

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

52. Section 21.5 is revised to read as follows:

§ 21.5 Communications.

Except where otherwise specified in this part, written communications and reports concerning the regulations in this part must be addressed to the NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail to EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee or permit holder, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

53. In § 21.21 the introductory text of paragraphs (a)(3) and (a)(3)(i), and paragraphs (d)(1)(i), (d)(1)(ii), and (d)(4)(vi) are revised and paragraph (d)(4)(ix) is added to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a)* * *

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraphs (a)(1) or (a)(2) of this section if the manufacture, construction, or operation of a facility or activity, a basic component supplied for such facility or activity, or the design certification or design approval under part 52 of this chapter-

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission or standard design approval under part 52 of this chapter, relating to a substantial safety hazard, or

* * * * *

(d)(1)* * *

(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

(4)* * *

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

* * * * *

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

* * * * *

54. In § 21.51 paragraphs (a)(4) and (a)(5) are added and paragraph (b) is revised to read as follows:

§ 21.51 Maintenance and inspection of records.

(a)* * *

(4) Applicants for standard design certification under subpart B of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.

(5) Applicants for or holders of a standard design approval under subpart E of part 52 of this chapter and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

55. In § 21.61, paragraph (b) is revised to read as follows:

§ 21.61 Failure to notify.

* * * * *

(b) Any NRC licensee or applicant for a license (including an applicant for, or holder of, a permit), applicant for a design certification under part 52 of this chapter during the pendency of its application, applicant for a design certification after Commission adoption of a final design certification rule for that design, or applicant for or holder of a standard design approval under part 52 of this chapter subject to the regulations in this part who fail to provide the notice required by § 21.21, or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by Section 234 of the Atomic Energy Act of 1954, as amended.

* * * * *

PART 25 - ACCESS AUTHORIZATION

56. The authority citation for Part 25 continues to read as follows:

AUTHORITY: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); E.O. 10865, as amended, 3 CFR 1959-1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12829, 3 CFR, 1993 Comp., p. 570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p. 333 as amended by E.O. 13292, 3 CFR 2004 Comp., p. 196; E.O. 12968, 3 CFR, 1995 Comp, p. 396.

Appendix A also issued under 96 Stat. 1051 (31 U.S.C. 9701).

57. The heading of Part 25 is revised to read as set forth above.

58. In § 25.35, paragraph (a) is revised to read as follows:

§ 25.35 Classified visits.

(a) The number of classified visits must be held to a minimum. The licensee, certificate holder, applicant for a standard design certification under part 52 of this chapter (including an applicant after the Commission has adopted a final standard design certification rule under part 52 of this chapter), or other facility, or an applicant for or holder of a standard design approval under part 52 of this chapter shall determine that the visit is necessary and that the purpose of the visit cannot be achieved without access to, or disclosure of, classified information. All classified visits require advance notification to, and approval of, the organization to be visited. In urgent cases, visit information may be furnished by telephone and confirmed in writing.

* * * * *

PART 26 - FITNESS FOR DUTY PROGRAMS

59. The authority citation for Part 26 continues to read as follows:

AUTHORITY: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201, 2297f); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

60. In § 26.2, the introductory text of paragraph (a), and paragraph (c) are revised to read as follows:

§ 26.2 Scope.

(a) The regulations in this part apply to licensees authorized to operate a nuclear power reactor, including a holder of a combined license after the Commission makes the finding under § 52.103(g) of this chapter, and licensees who are authorized to possess or use formula quantities of SSNM, or to transport formula quantities of SSNM. Each licensee shall implement a fitness-for-duty program which complies with this part. The provisions of the fitness-for-duty program must apply to all persons granted unescorted access to nuclear power plant protected areas, to licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures, and to SSNM licensee and transporter personnel who:

* * * * *

(c) Certain regulations in this part apply to licensees holding permits to construct a nuclear power plant, including a holder of a combined license before the date that the Commission makes the finding under § 52.103(g) of this chapter, holders of manufacturing licenses under part 52, and persons authorized to conduct the activities under § 50.10(e)(3) of this chapter. Each licensee with a construction permit, a combined license before the Commission makes the finding under § 52.103(g) of this chapter, a manufacturing license, or person authorized to conduct the activities under § 50.10(e)(3) of this chapter, with a plant or reactor under active construction or manufacture, shall—

- (1) Comply with §§ 26.10, 26.20, 26.23, 26.70, and 26.73;
- (2) Implement a chemical testing program, including random tests; and
- (3) Make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and recordkeeping.

* * * * *

61. In § 26.10, paragraph (a) is revised to read as follows:

§ 26.10 General performance objectives.

* * * * *

(a) Provide reasonable assurance that nuclear power plant personnel, personnel of a holder of a manufacturing license, personnel of a person authorized to conduct activities under § 50.10(e)(3) of this chapter, transporter personnel, and personnel of licensees authorized to possess or use formula quantities of SSNM, will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

* * * * *

62. In Appendix A of Part 26, paragraph (1) of Section 1.1 of Subpart A is revised to read as follows:

APPENDIX A TO PART 26 – GUIDELINES FOR DRUG AND ALCOHOL TESTING PROGRAMS

1.1 Applicability.

(1) These guidelines apply to licensees authorized to operate nuclear power reactors, including a holder of a combined license after the Commission makes the finding under § 52.103(g) of this chapter, and licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM).

* * * * *

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

63. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

64. In Section 50.2, definitions of *applicant*, *license*, *licensee*, and *prototype plant*, are added to read as follows:

§ 50.2 Definitions.

* * * * *

Applicant means a person or an entity applying for a license, permit, or other form of Commission permission or approval under this part or part 52 of this chapter.

* * * * *

License means a license, including a construction permit or operating license under this part, an early site permit, combined license or manufacturing license under part 52 of this chapter, or a renewed license issued by the Commission under this part, part 52, or part 54 of this chapter.

Licensee means a person who is authorized to conduct activities under a license issued by the Commission.

* * * * *

Prototype plant means a nuclear reactor that is used to test design features, such as the testing required under § 50.43(e). The prototype plant is similar to a first-of-a-kind or standard plant design in all features and size, but may include additional safety features to protect the public and the plant staff from the possible consequences of accidents during the testing period.

* * * * *

65. In § 50.10 the introductory text of paragraphs (b) and (c), and paragraphs (e)(1), (e)(2), and (e)(3) are revised to read as follows:

§ 50.10 License required.

* * * * *

(b) No person shall begin the construction of a production or utilization facility on a site on which the facility is to be operated until either a construction permit under this part, or a combined license under subpart C of part 52 of this chapter has been issued. As used in this paragraph, the term “construction” includes pouring the foundation for, or the installation of, any portion of the permanent facility on the site, but does not include:

* * * * *

(c) Notwithstanding the provisions of paragraph (b) of this section, and subject to paragraphs (d) and (e) of this section, no person shall effect commencement of construction of a production or utilization facility subject to the provisions of § 51.20(b) of this chapter on a site on which the facility is to be operated until an early site permit, construction permit, or combined license has been issued. As used in this paragraph, the term “commencement of construction” means any clearing of land, excavation or other substantial action that would adversely affect the environment of a site, but does not include:

* * * * *

(e)(1) The Director of Nuclear Reactor Regulation may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b)(2) or (3), or § 50.22 or is a testing facility, or an applicant for a combined license to conduct the following activities:

(i) Preparation of the site for construction of the facility (including activities as clearing, grading, construction of temporary access roads and borrow areas);

(ii) Installation of temporary construction support facilities (including items such as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings);

(iii) Excavation for facility structures;

(iv) Construction of service facilities (including facilities such as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines, and sanitary sewerage treatment facilities); and

(v) The construction of structures, systems and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

(2) No authorization shall be granted unless the staff has completed a final environmental impact statement on the issuance of the construction permit or combined license as required by subpart A of part 51 of this chapter. An authorization shall be granted only after the presiding officer in the proceeding on the construction permit or combined license application:

(i) Has made all the findings required by §§ 51.104(b), 51.105, and 51.107 of this chapter to be made before issuance of the construction permit, or combined license for the facility; and

(ii) Has determined that, based upon the available information and review to date, there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type proposed from the standpoint of radiological health and safety considerations under the Act and regulations issued by the Commission.

(3)(i) The Director of New Reactors or the Director of Nuclear Reactor Regulation, as appropriate, may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b)(2) or (3), or § 50.22 or is a testing facility, or an applicant for a combined license to conduct, in addition to the activities described in paragraph (e)(1) of this section, the installation of structural foundations, including any necessary subsurface preparation, for structures, systems, and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

(ii) Such an authorization, which may be combined with the authorization described in paragraph (e)(1) of this section, or may be granted at a later time, shall be granted only after the presiding officer in the proceeding on the construction permit or combined license application has, in addition to making the findings and determinations required by paragraph (e)(2) of this section, determined that there are no unresolved safety issues relating

to the additional activities that may be authorized under this paragraph that would constitute good cause for withholding authorization.

* * * * *

66. Section 50.23 is revised to read as follows:

§ 50.23 Construction permits.

A construction permit for the construction of a production or utilization facility will be issued before the issuance of a license if the application is otherwise acceptable, and will be converted upon completion of the facility and Commission action, into a license as provided in § 50.56. However, if a combined license for a nuclear power reactor is issued under part 52 of this chapter, the construction permit and operating license are deemed to be combined in a single license. A construction permit for the alteration of a production or utilization facility will be issued before the issuance of an amendment of a license, if the application for amendment is otherwise acceptable, as provided in § 50.91.

67. The undesignated center heading before § 50.30 is revised as follows:

Applications for Licenses, Certifications, and Regulatory Approvals; Form; Contents;
Ineligibility of Certain Applicants

68. In § 50.30, the section heading and paragraphs (a)(1), (a)(3), (a)(5), (a)(6), (b), (e), and (f) are revised to read as follows:

§ 50.30 Filing of application; oath or affirmation.

(a)* * *

(1) Each filing of an application for a standard design approval or license to construct and/or operate, or manufacture, a production or utilization facility (including an early site permit,

combined license, and manufacturing license under part 52 of this chapter), and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission in accordance with § 50.4 or § 52.3 of this chapter, as applicable.

* * * * *

(3) Each applicant for a construction permit under this part, or an early site permit, combined license, or manufacturing license under part 52 of this chapter, shall, upon notification by the Atomic Safety and Licensing Board appointed to conduct the public hearing required by the Atomic Energy Act, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by the Atomic Safety and Licensing Board. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the U.S. Nuclear Regulatory Commission as specified in § 50.4 or § 52.3 of this chapter, as applicable.

* * * * *

(5) At the time of filing an application, the Commission will make available at the NRC Web site, <http://www.nrc.gov>, a copy of the application, subsequent amendments, and other records pertinent to the matter which is the subject of the application for public inspection and copying.

(6) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 50.4 or § 52.3 of this chapter, as applicable, to enable the Director, Office of New Reactors, or the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate, to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation.* Each application for a standard design approval or license, including, whenever appropriate, a construction permit or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

* * * * *

(e) *Filing Fees.* Each application for a standard design approval or production or utilization facility license, including, whenever appropriate, a construction permit or early site permit, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in part 170 of this chapter. No fee will be required to accompany an application for renewal, amendment, or termination of a construction permit, operating license, combined license, or manufacturing license, except as provided in § 170.21 of this chapter.

(f) *Environmental report.* An application for a construction permit, operating license, early site permit, combined license, or manufacturing license for a nuclear power reactor, testing facility, fuel reprocessing plant, or other production or utilization facility whose construction or operation may be determined by the Commission to have a significant impact in the environment, shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

69. In § 50.33, paragraphs (f)(3) and (f)(4) are redesignated as (f)(4) and (f)(5), respectively, and are revised, a new paragraph (f)(3) is added, and paragraphs (g), (h), and (k)(1) are revised to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(f)* * *

(3) If the application is for a combined license under subpart C of part 52 of this chapter, the applicant shall submit the information described in paragraphs (f)(1) and (f)(2) of this section.

(4) Each application for a construction permit, operating license, or combined license submitted by a newly-formed entity organized for the primary purpose of constructing and/or operating a facility must also include information showing:

(i) The legal and financial relationships it has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(5) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(g) If the application is for an operating license or combined license for a nuclear power reactor, or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, the applicant shall submit radiological emergency response plans of State and local governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),⁴ as

⁴Emergency planning zones (EPZs) are discussed in NUREG-0396, EPA 520/1-78-016, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-Water Nuclear Power Plants," December 1978.

well as the plans of State governments wholly or partially within the ingestion pathway EPZ.⁵ If the application is for an early site permit that, under 10 CFR 52.17(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must meet the requirements of this paragraph. Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ shall consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 MW thermal. The plans for the ingestion pathway shall focus on such actions as are appropriate to protect the food ingestion pathway.

(h) If the applicant, other than an applicant for a combined license, proposes to construct or alter a production or utilization facility, the application shall state the earliest and latest dates for completion of the construction or alteration.

* * * * *

(k)(1) For an application for an operating license or combined license for a production or utilization facility, information in the form of a report, as described in § 50.75, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

* * * * *

⁵If the State and local emergency response plans have been previously provided to the NRC for inclusion in the facility docket, the applicant need only provide the appropriate reference to meet this requirement.

70. In § 50.34, the section heading, the introductory text of paragraph (a)(1), paragraphs (a)(1)(ii)(E) and (a)(12), the introductory text of paragraph (b), paragraphs (b)(10) and (b)(11), and paragraphs (c), (d), and (e), the introductory text of paragraphs (f) and (f)(1), and paragraphs (g), and (h)(1)(ii) are revised to read as follows:

§ 50.34 Contents of construction permit and operating license applications; technical information.

(a)* * *

(1) Stationary power reactor applicants for a construction permit who apply on or after January 10, 1997, shall comply with paragraph (a)(1)(ii) of this section. All other applicants for a construction permit shall comply with paragraph (a)(1)(i) of this section.

* * * * *

(ii)* * *

(E) With respect to operation at the projected initial power level, the applicant is required to submit information prescribed in paragraphs (a)(2) through (a)(8) of this section, as well as the information required by paragraph (a)(1)(i) of this section, in support of the application for a construction permit.

* * * * *

(12) On or after January 10, 1997, stationary power reactor applicants who apply for a construction permit, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria in appendix S to this part.

(b) *Final safety analysis report.* Each application for an operating license shall include a final safety analysis report. The final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and shall include the following:

* * * * *

(10) On or after January 10, 1997, stationary power reactor applicants who apply for an operating license, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria of appendix S to this part. However, for those operating license applicants and holders whose construction permit was issued before January 10, 1997, the earthquake engineering criteria in Section VI of appendix A to part 100 of this chapter continues to apply.

(11) On or after January 10, 1997, stationary power reactor applicants who apply for an operating license, shall provide a description and safety assessment of the site and of the facility as in § 50.34(a)(1)(ii). However, for either an operating license applicant or holder whose construction permit was issued before January 10, 1997, the reactor site criteria in part 100 of this chapter and the seismic and geologic siting criteria in appendix A to part 100 of this chapter continues to apply.

(c) *Physical Security Plan.* Each application for an operating license for a production or utilization facility must include a physical security plan. The plan must describe how the applicant will meet the requirements of part 73 of this chapter (and part 11 of this chapter, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(d) *Safeguards contingency plan.* Each application for an operating license for a production or utilization facility that will be subject to §§ 73.50, 73.55, or § 73.60 of this chapter, must include a licensee safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to

the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for such a license shall include the first four categories of information contained in the applicant's safeguards contingency plan. (The first four categories of information as set forth in appendix C to 10 CFR part 73 of this chapter are Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix. The fifth category of information, Procedures, does not have to be submitted for approval.)⁹

(e) *Protection against unauthorized disclosure.* Each applicant for an operating license for a production or utilization facility, who prepares a physical security plan, a safeguards contingency plan, or a guard qualification and training plan, shall protect the plans and other related safeguards information against unauthorized disclosure in accordance with the requirements of § 73.21 of this chapter, as appropriate.

(f) *Additional TMI-related requirements.* In addition to the requirements of paragraph (a) of this section, each applicant for a light-water-reactor construction permit or manufacturing license whose application was pending as of February 16, 1982, shall meet the requirements in paragraphs (f)(1) through (3) of this section. This regulation applies to the pending applications by Duke Power Company (Perkins Nuclear Station, Units 1, 2, and 3), Houston Lighting & Power Company (Allens Creek Nuclear Generating Station, Unit 1), Portland General Electric Company (Pebble Springs Nuclear Plant, Units 1 and 2), Public Service Company of Oklahoma (Black Fox Station, Units 1 and 2), Puget Sound Power & Light Company (Skagit/Hanford Nuclear Power Project, Units 1 and 2), and Offshore Power Systems (License to Manufacture Floating Nuclear Plants). The number of units that will be specified in the manufacturing license above, if issued, will be that number whose start of manufacture, as defined in the license application, can practically begin within a 10-year period commencing on

⁹A physical security plan that contains all the information required in both § 73.55 and appendix C to part 73 of this chapter satisfies the requirement for a contingency plan.

the date of issuance of the manufacturing license, but in no event will that number be in excess of ten. The manufacturing license will require the plant design to be updated no later than 5 years after its approval. Paragraphs (f)(1)(xii), (2)(ix), and (3)(v) of this section, pertaining to hydrogen control measures, must be met by all applicants covered by this regulation. However, the Commission may decide to impose additional requirements and the issue of whether compliance with these provisions, together with 10 CFR 50.44 and criterion 50 of appendix A to 10 CFR part 50, is sufficient for issuance of that manufacturing license which may be considered in the manufacturing license proceeding. In addition, each applicant for a design certification, design approval, combined license, or manufacturing license under part 52 of this chapter shall demonstrate compliance with the technically relevant portions of the requirements in paragraphs (f)(1) through (3) of this section, except for paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v).

(1) To satisfy the following requirements, the application shall provide sufficient information to describe the nature of the studies, how they are to be conducted, estimated submittal dates, and a program to ensure that the results of these studies are factored into the final design of the facility. For licensees identified in the introduction to paragraph (f) of this section, all studies must be completed no later than 2 years following the issuance of the construction permit or manufacturing license.¹⁰ For all other applicants, the studies must be submitted as part of the final safety analysis report.

* * * * *

(g) *Combustible gas control.* All applicants for a reactor construction permit or operating license whose application is submitted after October 16, 2003, shall include the

¹⁰Alphanumeric designations correspond to the related action plan items in NUREG 0718 and NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident." They are provided herein for information only.

analyses, and the descriptions of the equipment and systems required by § 50.44 as a part of their application.

(h)* * *

(1)* * *

(ii) Applications for light-water-cooled nuclear power plant construction permits docketed after May 17, 1982, shall include an evaluation of the facility against the SRP in effect on May 17, 1982, or the SRP revision in effect six months before the docket date of the application, whichever is later.

* * * * *

71. Section 50.34a is revised to read as follows:

§ 50.34a Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors.

(a) An application for a construction permit shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, including expected operational occurrences. In the case of an application filed on or after January 2, 1971, the application shall also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as is reasonably achievable. The term “as low as is reasonably achievable” as used in this part means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest. The guides set out in appendix I to this part provide numerical guidance on design objectives for light-water-cooled nuclear power reactors to meet the requirements that radioactive material in effluents

released to unrestricted areas be kept as low as is reasonably achievable. These numerical guides for design objectives and limiting conditions for operation are not to be construed as radiation protection standards.

(b) Each application for a construction permit shall include:

(1) A description of the preliminary design of equipment to be installed under paragraph (a) of this section;

(2) An estimate of:

(i) The quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations; and

(ii) The quantity of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations.

(3) A general description of the provisions for packaging, storage, and shipment offsite of solid waste containing radioactive materials resulting from treatment of gaseous and liquid effluents and from other sources.

(c) Each application for an operating license shall include:

(1) A description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) A revised estimate of the information required in paragraph (b)(2) of this section if the expected releases and exposures differ significantly from the estimates submitted in the application for a construction permit.

(d) Each application for a combined license under part 52 of this chapter shall include:

(1) A description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) The information required in paragraph (b)(2) of this section.

(e) Each application for a design approval, a design certification, or a manufacturing license under part 52 of this chapter shall include:

(1) A description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) The information required in paragraph (b)(2) of this section.

72. In § 50.36, current paragraphs (c), (d), and (e) are redesignated as paragraphs (d), (e), and (f), respectively, and a new paragraph (c) is added to read as follows:

§ 50.36 Technical specifications.

* * * * *

(c) Each applicant for a design certification or manufacturing license under part 52 of this chapter shall include in its application proposed generic technical specifications in accordance with the requirements of this section for the portion of the plant that is within the scope of the design certification or manufacturing license application.

* * * * *

73. In § 50.36a, paragraph (a) is revised to read as follows:

§ 50.36a Technical specifications on effluents from nuclear power reactors.

(a) To keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable, each licensee

of a nuclear power reactor and each applicant for a design certification or a manufacturing license will include technical specifications that, in addition to requiring compliance with applicable provisions of § 20.1301 of this chapter, require that:

(1) Operating procedures developed pursuant to § 50.34a(c) for the control of effluents be established and followed and that the radioactive waste system, pursuant to § 50.34a, be maintained and used. The licensee shall retain the operating procedures in effect as a record until the Commission terminates the license and shall retain each superseded revision of the procedures for 3 years from the date it was superseded.

(2) Each holder of an operating license, and each holder of a combined license after the Commission has made the finding under § 52.103(g) of this chapter, shall submit a report to the Commission annually that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous 12 months, including any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases. The report must be submitted as specified in § 50.4, and the time between submission of the reports must be no longer than 12 months. If quantities of radioactive materials released during the reporting period are significantly above design objectives, the report must cover this specifically. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

* * * * *

74. Section 50.36b is revised to read as follows:

§ 50.36b Environmental conditions.

(a) Each construction permit under this part, each early site permit under part 52 of this chapter, and each combined license under part 52 of this chapter may include conditions to protect the environment during construction. These conditions are to be set out in an attachment to the permit or license, which is incorporated in and made a part of the permit or license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 51.50 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirements for the protection of the nonaquatic environment.

(b) Each license authorizing operation of a production or utilization facility, including a combined license under part 52 of this chapter, and each license for a nuclear power reactor facility for which the certification of permanent cessation of operations required under § 50.82(a)(1) or § 52.110(a) of this chapter has been submitted, which is of a type described in § 50.21(b)(2) or (3) or § 50.22 or is a testing facility, may include conditions to protect the environment during operation and decommissioning. These conditions are to be set out in an attachment to the license which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted pursuant to §§51.50 and 51.53 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirements for the protection of the nonaquatic environment.

75. Section 50.37 is revised to read as follows:

§ 50.37 Agreement limiting access to Classified Information.

As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license, construction permit, early site permit, or standard design approval, or before the Commission has adopted a final standard design certification rule under part 52 of this chapter, the applicant shall agree in writing that it will not permit any individual to have access to any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license, or construction permit, or standard design approval.

76. The undesignated center heading before § 50.40 is revised as follows:

Standards for Licenses, Certifications, and Regulatory Approvals

77. Section 50.40 is revised to read as follows:

§ 50.40 Common standards.

In determining that a construction permit or operating license in this part, or early site permit, combined license, or manufacturing license in part 52 of this chapter will be issued to an applicant, the Commission will be guided by the following considerations:

(a) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in part 20 of this chapter, and that the health and safety of the public will not be endangered.

(b) The applicant for a construction permit, operating license, combined license, or manufacturing license is technically and financially qualified to engage in the proposed activities

in accordance with the regulations in this chapter. However, no consideration of financial qualification is necessary for an electric utility applicant for an operating license for a utilization facility of the type described in § 50.21(b) or § 50.22 or for an applicant for a manufacturing license.

(c) The issuance of a construction permit, operating license, early site permit, combined license, or manufacturing license to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.

(d) Any applicable requirements of subpart A of 10 CFR part 51 have been satisfied.

78. In § 50.43, the section heading, the introductory paragraph, and paragraph (d) are revised, and paragraph (e) is added to read as follows:

§ 50.43 Additional standards and provisions affecting class 103 licenses and certifications for commercial power.

In addition to applying the standards set forth in §§ 50.40 and 50.42, paragraphs (a) through (e) of this section apply in the case of a class 103 license for a facility for the generation of commercial power. For a design certification under part 52 of this chapter, only paragraph (e) of this section applies.

* * * * *

(d) Nothing shall preclude any government agency, now or hereafter authorized by law to engage in the production, marketing, or distribution of electric energy, if otherwise qualified, from obtaining a construction permit or operating license under this part, or a combined license under part 52 of this chapter for a utilization facility for the primary purpose of producing electric energy for disposition for ultimate public consumption.

(e) Applications for a design certification, combined license, manufacturing license, or operating license that propose nuclear reactor designs which differ significantly from light-water

reactor designs that were licensed before 1997, or use simplified, inherent, passive, or other innovative means to accomplish their safety functions, will be approved only if:

(1)(i) The performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof;

(ii) Interdependent effects among the safety features of the design are acceptable, as demonstrated by analysis, appropriate test programs, experience, or a combination thereof; and

(iii) Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions; or

(2) There has been acceptable testing of a prototype plant over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. If a prototype plant is used to comply with the testing requirements, then the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to protect the public and the plant staff from the possible consequences of accidents during the testing period.

79. Section 50.45 is revised to read as follows:

§ 50.45 Standards for construction permits, operating licenses, and combined licenses.

(a) An applicant for an operating license or an amendment of an operating license who proposes to construct or alter a production or utilization facility will be initially granted a construction permit if the application is in conformity with and acceptable under the criteria of §§ 50.31 through 50.38, and the standards of §§ 50.40 through 50.43, as applicable.

(b) A holder of a combined license who proposes, after the Commission makes the finding under § 52.103(g) of this chapter, to alter the licensed facility will be initially granted a construction permit if the application is in conformity with and acceptable under the criteria of

§§ 50.30 through 50.33, § 50.34(f), §§ 50.34a through 50.38, the standards of §§ 50.40 through 50.43, as applicable, and §§ 52.79 and 52.80 of this chapter.

80. In § 50.46, paragraph (a)(3) is revised to read as follows:

§ 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.

(a)* * *

(3)(i) Each applicant for or holder of an operating license or construction permit issued under this part, applicant for a standard design certification under part 52 of this chapter (including an applicant after the Commission has adopted a final design certification regulation), or an applicant for or holder of a standard design approval, a combined license or a manufacturing license issued under part 52 of this chapter, shall estimate the effect of any change to or error in an acceptable evaluation model or in the application of such a model to determine if the change or error is significant. For this purpose, a significant change or error is one which results in a calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F.

(ii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a construction permit, operating license, combined license, or manufacturing license shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission at least annually as specified in § 50.4 or § 52.3 of this chapter, as applicable. If the change or error is significant, the applicant or licensee shall provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking

other action as may be needed to show compliance with § 50.46 requirements. This schedule may be developed using an integrated scheduling system previously approved for the facility by the NRC. For those facilities not using an NRC approved integrated scheduling system, a schedule will be established by the NRC staff within 60 days of receipt of the proposed schedule. Any change or error correction that results in a calculated ECCS performance that does not conform to the criteria set forth in paragraph (b) of this section is a reportable event as described in §§ 50.55(e), 50.72, and 50.73. The affected applicant or licensee shall propose immediate steps to demonstrate compliance or bring plant design or operation into compliance with § 50.46 requirements.

(iii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a standard design approval or the applicant for a standard design certification (including an applicant after the Commission has adopted a final design certification rule) shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission and to any applicant or licensee referencing the design approval or design certification at least annually as specified in § 52.3 of this chapter. If the change or error is significant, the applicant or holder of the design approval or the applicant for the design certification shall provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. The affected applicant or holder shall propose immediate steps to demonstrate compliance or bring plant design into compliance with § 50.46 requirements.

* * * * *

81. In § 50.47, paragraph (a)(1) is revised and paragraph (e) is added to read as follows:

§ 50.47 Emergency plans.

(a)(1)(i) Except as provided in paragraph (d) of this section, no initial operating license for a nuclear power reactor will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed nuclear power reactor operating license.

(ii) No initial combined license under part 52 of this chapter will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed combined license.

(iii) If an application for an early site permit under subpart A of part 52 of this chapter includes complete and integrated emergency plans under 10 CFR 52.17(b)(2)(ii), no early site permit will be issued unless a finding is made by the NRC that the emergency plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(iv) If an application for an early site permit proposes major features of the emergency plans under 10 CFR 52.17(b)(2)(i), no early site permit will be issued unless a finding is made by the NRC that the major features are acceptable in accordance with the applicable standards of 10 CFR 50.47 and 10 CFR part 50, appendix E, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

(e) Notwithstanding the requirements of paragraph (b) of this section and the provisions of § 52.103 of this chapter, a holder of a combined license under part 52 of this chapter may

not load fuel or operate except as provided in accordance with appendix E to part 50 and § 50.54(gg).

82. In § 50.48, the introductory text of paragraph (a)(1) is revised to read as follows:

§ 50.48 Fire protection.

(a)(1) Each holder of an operating license issued under this part or a combined license issued under part 52 of this chapter must have a fire protection plan that satisfies Criterion 3 of appendix A to this part. This fire protection plan must:

* * * * *

83. In § 50.49, paragraph (a) is revised to read as follows:

§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

(a) Each holder of or an applicant for an operating license issued under this part, or a combined license or manufacturing license issued under part 52 of this chapter, other than a nuclear power plant for which the certifications required under § 50.82(a)(1) or § 52.110(a)(1) of this chapter have been submitted, shall establish a program for qualifying the electric equipment defined in paragraph (b) of this section. For a manufacturing license, only electric equipment defined in paragraph (b) which is within the scope of the manufactured reactor must be included in the program.

* * * * *

84. In § 50.54, the introductory text, and paragraphs (a)(1), (i-1), (o), (p), and (q) are revised and paragraph (gg) is added to read as follows:

§ 50.54 Conditions of licenses.

The following paragraphs with the exception of paragraphs (r) and (gg) of this section are conditions in every nuclear power reactor operating license issued under this part. The following paragraphs with the exception of paragraph (r), (s), and (u) of this section are conditions in every combined license issued under part 52 of this chapter, *provided, however*, that paragraphs (i), (i-1), (j), (k), (l), (m), (n), (w), (x), (y), and (z) of this section are only applicable after the Commission makes the finding under § 52.103(g) of this chapter.

(a)(1) Each nuclear power plant or fuel reprocessing plant licensee subject to the quality assurance criteria in appendix B of this part shall implement, under § 50.34(b)(6)(ii) or § 52.79 of this chapter, the quality assurance program described or referenced in the safety analysis report, including changes to that report. However, a holder of a combined license under part 52 of this chapter shall implement the quality assurance program described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for the initial loading of fuel.

* * * * *

(i-1) Within 3 months after either the issuance of an operating license or the date that the Commission makes the finding under § 52.103(g) of this chapter for a combined license, as applicable, the licensee shall have in effect an operator requalification program. The operator requalification program must, as a minimum, meet the requirements of § 55.59(c) of this chapter. Notwithstanding the provisions of § 50.59, the licensee may not, except as specifically authorized by the Commission decrease the scope of an approved operator requalification program.

* * * * *

(o) Primary reactor containments for water cooled power reactors, other than facilities for which the certifications required under §§ 50.82(a)(1) or 52.110(a)(1) of this chapter have been submitted, shall be subject to the requirements set forth in appendix J to this part.

(p)(1) The licensee shall prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for effecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may make no change which would decrease the effectiveness of a security plan, or guard training and qualification plan, prepared pursuant to § 50.34(c) or § 52.79(a), or part 73 of this chapter, or of the first four categories of information (Background, Generic Planning Base, Licensee Planning Base, Responsibility Matrix) contained in a licensee safeguards contingency plan prepared pursuant to § 50.34(d) or § 52.79(a) or part 73 of this chapter, as applicable, without prior approval of the Commission. A licensee desiring to make such a change shall submit an application for an amendment to the licensee's license pursuant to § 50.90.

(2) The licensee may make changes to the plans referenced in paragraph (p)(1) of this section, without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee shall maintain records of changes to the plans made without prior Commission approval for a period of 3 years from the date of the change, and shall submit, as specified in § 50.4 or § 52.3 of this chapter, a report containing a description of each change within 2 months after the change is made. Prior to the safeguards contingency plan being put into effect, the licensee shall have:

(i) All safeguards capabilities specified in the safeguards contingency plan available and functional;

(ii) Detailed procedures developed according to appendix C to part 73 of this chapter available at the licensee's site; and

(iii) All appropriate personnel trained to respond to safeguards incidents as outlined in the plan and specified in the detailed procedures.

(3) The licensee shall provide for the development, revision, implementation, and maintenance of its safeguards contingency plan. The licensee shall ensure that all program elements are reviewed by individuals independent of both security program management and personnel who have direct responsibility for implementation of the security program either:

(i) At intervals not to exceed 12 months; or

(ii) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect security, but no longer than 12 months after the change. In any case, all elements of the safeguards contingency plan must be reviewed at least once every 24 months.

(4) The review must include a review and audit of safeguards contingency procedures and practices, an audit of the security system testing and maintenance program, and a test of the safeguards systems along with commitments established for response by local law enforcement authorities. The results of the review and audit, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and kept available at the plant for inspection for a period of 3 years.

(q) A holder of a nuclear power reactor operating license under this part, or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall follow and maintain in effect emergency plans which meet the standards in § 50.47(b) and the requirements in appendix E of this part. A licensee authorized to possess and/or operate a research reactor or a fuel facility shall follow and maintain in effect emergency plans which meet the requirements in appendix E to this part. The licensee shall retain the emergency plan and each change that decreases the effectiveness of the plan as a record until

the Commission terminates the license for the nuclear power reactor. The nuclear power reactor licensee may make changes to these plans without Commission approval only if the changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of § 50.47(b) and the requirements of appendix E to this part. The research reactor and/or the fuel facility licensee may make changes to these plans without Commission approval only if these changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the requirements of appendix E to this part. This nuclear power reactor, research reactor, or fuel facility licensee shall retain a record of each change to the emergency plan made without prior Commission approval for a period of 3 years from the date of the change. Proposed changes that decrease the effectiveness of the approved emergency plans may not be implemented without application to and approval by the Commission. The licensee shall submit, as specified in § 50.4, a report of each proposed change for approval. If a change is made without approval, the licensee shall submit, as specified in § 50.4, a report of each change within 30 days after the change is made.

* * * * *

(gg)(1) Notwithstanding 10 CFR 52.103, if following the conduct of the exercise required by paragraph IV.f.2.a of appendix E to part 50 of this chapter, DHS identifies one or more deficiencies in the state of offsite emergency preparedness, the holder of a combined license under 10 CFR part 52 may operate at up to 5 percent of rated thermal power only if the Commission finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC will base this finding on its assessment of the applicant's onsite emergency plans against the pertinent standards in § 50.47 and appendix E to this part. Review of the applicant's emergency plans will include the following standards with offsite aspects:

(i) Arrangements for requesting and effectively using offsite assistance onsite have been made, arrangements to accommodate State and local staff at the licensee's near-site Emergency Operations Facility have been made, and other organizations capable of augmenting the planned onsite response have been identified.

(ii) Procedures have been established for licensee communications with State and local response organizations, including initial notification of the declaration of emergency and periodic provision of plant and response status reports.

(iii) Provisions exist for prompt communications among principal response organizations to offsite emergency personnel who would be responding onsite.

(iv) Adequate emergency facilities and equipment to support the emergency response onsite are provided and maintained.

(v) Adequate methods, systems, and equipment for assessing and monitoring actual or potential offsite consequences of a radiological emergency condition are in use onsite.

(vi) Arrangements are made for medical services for contaminated and injured onsite individuals.

(vii) Radiological emergency response training has been made available to those offsite who may be called to assist in an emergency onsite.

(2) The condition in this paragraph, regarding operation at up to 5 percent power, ceases to apply 30 days after DHS informs the NRC that the offsite deficiencies have been corrected, unless the NRC notifies the combined license holder before the expiration of the 30-day period that the Commission finds under paragraphs (s)(2) and (3) of this section that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

85. In § 50.55, the heading, the introductory text and paragraphs (a), (b), (c), and (e) are revised, and a new paragraph (f)(4) is added to read as follows:

§ 50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.

Each construction permit is subject to the following terms and conditions; each early site permit is subject to the terms and conditions in paragraph (f) of this section; each manufacturing license is subject to the terms and conditions in paragraphs (e) and (f) of this section; and each combined license is subject to the terms and conditions in paragraphs (e) and (f) of this section until the date that the Commission makes the finding under § 52.103(g) of this chapter:

(a) The construction permit shall state the earliest and latest dates for completion of the construction or modification.

(b) If the proposed construction or modification of the facility is not completed by the latest completion date, the construction permit shall expire and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributable to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

* * * * *

(e)(1) *Definitions.* For purposes of this paragraph, the definitions in § 21.3 of this chapter apply.

(2) *Posting requirements.* (i) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of the regulations in this part; Section 206 of the Energy Reorganization Act of 1974 (ERA); and

procedures adopted under the regulations in this part. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(ii) If posting of the regulations in this part or the procedures adopted under the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting Section 206 of the ERA, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where the regulation, procedures, and reports may be examined.

(3) *Procedures.* Each individual, corporation, partnership, or other entity holding a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license under 10 CFR part 52 must adopt appropriate procedures to—

(i) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (e)(3)(ii) of this section, in all cases within 60 days of discovery, to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(ii) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in paragraph (e)(4)(v) of this section. The interim report should describe the deviation or failure to comply that it is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(iii) Ensure that a director or responsible officer of the holder of a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license under 10 CFR part 52 is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (e)(3)(i) or (e)(3)(ii) of this section, if the construction or manufacture of a facility or activity, or a basic component supplied for such facility or activity—

(A) Fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission, relating to a substantial safety hazard;

(B) Contains a defect; or

(C) Undergoes any significant breakdown in any portion of the quality assurance program conducted under the requirements of appendix B to 10 CFR part 50 which could have produced a defect in a basic component. These breakdowns in the quality assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture.

(4) *Notification.*

(i) The holder of a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license who obtains information reasonably indicating that the facility fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director or responsible officer or designated person as discussed in paragraph (e)(10) of this section.

(ii) The holder of a facility construction permit subject to this part, combined license, or manufacturing license, who obtains information reasonably indicating the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility as approved and released for construction or manufacture, must notify the Commission

of the defect through a director or responsible officer or designated person as discussed in paragraph (e)(4)(v) of this section.

(iii) The holder of a facility construction permit subject to this part, combined license, or manufacturing license, who obtains information reasonably indicating that the quality assurance program has undergone any significant breakdown discussed in paragraph (e)(3)(ii)(C) of this section must notify the Commission of the breakdown in the quality assurance program through a director or responsible officer or designated person as discussed in paragraph (4)(v) of this section.

(iv) A dedicating entity is responsible for identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and maintaining auditable records for the dedication process.

(v) The notification requirements of this paragraph apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the safety analysis report, construction permit, combined license, or manufacturing license. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the construction permit holder's, combined license holder's, and manufacturing license holder's evaluation and notification obligations under part 21 of this chapter, and satisfies the responsibility of individual directors or responsible officers of holders of construction permits issued under § 50.23, holders of combined licenses (until the Commission makes the finding under § 52.103 of this chapter), and holders of manufacturing licenses to report defects, and failures to comply associated with substantial safety hazards under Section 206 of the ERA. The director or responsible officer may authorize an individual to provide the notification required by this section, provided that this must not relieve the director or responsible officer of his or her responsibility under this section.

(5) *Notification — timing and where sent.* The notification required by paragraph (e)(4) of this section must consist of—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within 2 days following receipt of information by the director or responsible corporate officer under paragraph (e)(3)(iii) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in paragraph (e)(3)(ii) of this section.

(ii) Written notification submitted to the Document Control Desk, U.S. Nuclear Regulatory Commission, by an appropriate method listed in § 50.4, with a copy to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter and a copy to the appropriate NRC resident inspector within 30 days following receipt of information by the director or responsible corporate officer under paragraph (e)(3)(iii) of this section, on the identification of a defect or failure to comply.

(6) *Content of notification.* The written notification required by paragraph (e)(9)(ii) of this section must clearly indicate that the written notification is being submitted under § 50.55(e) and include the following information, to the extent known—

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.

(iii) Identification of the firm constructing or manufacturing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by the defect or failure to comply.

(v) The date on which the information of a defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all the basic components in use at the facility subject to the regulations in this part.

(vii) In the case of a completed reactor manufactured under part 52 of this chapter, the entities to which the reactor was supplied.

(viii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(ix) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to other entities.

(7) *Procurement documents.* Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component specifies or is issued by the entity subject to the regulations, when applicable, that the provisions of 10 CFR part 21 or 10 CFR 50.55(e) applies, as applicable.

(8) *Coordination with 10 CFR part 21.* The requirements of § 50.55(e) are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under part 21 of this chapter, under § 73.71 of this chapter, or under §§ 50.55(e) or 50.73. For holders of construction permits issued before October 29, 1991, evaluation, reporting and recordkeeping requirements of § 50.55(e) may be met by complying with the comparable requirements of part 21 of this chapter.

(9) *Records retention.* The holder of a construction permit, combined license, and manufacturing license must prepare and maintain records necessary to accomplish the purposes of this section, specifically—

(i) Retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the facility or basic component.

(ii) Retain records of evaluations of all deviations and failures to comply under paragraph (e)(3)(i) of this section for the longest of:

(A) Ten (10) years from the date of the evaluation;

(B) Five (5) years from the date that an early site permit is referenced in an application for a combined license; or

(C) Five (5) years from the date of delivery of a manufactured reactor.

(iii) Retain records of all interim reports to the Commission made under paragraph (e)(3)(ii) of this section, or notifications to the Commission made under paragraph (e)(4) of this section for the minimum time periods stated in paragraph (e)(9)(ii) of this section;

(iv) Suppliers of basic components must retain records of:

(A) All notifications sent to affected licensees or purchasers under paragraph (e)(4)(iv) of this section for a minimum of ten (10) years following the date of the notification;

(B) The facilities or other purchasers to whom basic components or associated services were supplied for a minimum of fifteen (15) years from the delivery of the basic component or associated services.

(v) Maintaining records in accordance with this section satisfies the recordkeeping obligations under part 21 of this chapter of the entities, including directors or responsible officers thereof, subject to this section.

(f)* * *

(4) Each holder of an early site permit or a manufacturing license under part 52 of this chapter shall implement the quality assurance program described or referenced in the safety

analysis report, including changes to that report. Each holder of a combined license shall implement the quality assurance program for design and construction described or referenced in the safety analysis report, including changes to that report, provided, however, that the holder of a combined license is not subject to the terms and conditions in this paragraph after the Commission makes the finding under § 52.103(g) of this chapter.

(i) Each holder described in paragraph (f)(4) of this section may make a change to a previously accepted quality assurance program description included or referenced in the safety analysis report, if the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the quality assurance program description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(A) Changes to the safety analysis report must be submitted for review as specified in § 50.4. Changes made to NRC-accepted quality assurance topical report descriptions must be submitted as specified in § 50.4.

(B) The submittal of a change to the safety analysis report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of appendix B of this part and the safety analysis report quality assurance program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the changes must be maintained as a facility record for three (3) years.

(D) Changes to the quality assurance program description included or referenced in the safety analysis report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(ii) [Reserved]

86. In Section 50.55a, the introductory paragraph, paragraphs (b)(1)(i), (b)(1)(ii), (b)(1)(iii), (b)(1)(v), the introductory text of paragraphs (b)(4) and (d)(1), paragraph (e)(1), the introductory text of paragraph (f)(3), paragraphs (f)(3)(iii), (f)(3)(iv)(B), (f)(4)(i), the introductory text of paragraph (g)(3), paragraphs (g)(4)(i), the introductory text of paragraph (g)(4)(v), and paragraph (h)(3) are revised to read as follows:

§ 50.55a Codes and standards.

Each construction permit for a utilization facility is subject to the following conditions in addition to those specified in § 50.55. Each combined license for a utilization facility is subject to the following conditions in addition to those specified in § 50.55, except that each combined license for a boiling or pressurized water-cooled nuclear power facility is subject to the conditions in paragraphs (f) and (g) of this section, but only after the Commission makes the finding under § 52.103(g) of this chapter. Each operating license for a boiling or pressurized water-cooled nuclear power facility is subject to the conditions in paragraphs (f) and (g) of this section in addition to those specified in § 50.55. Each manufacturing license, standard design approval, and standard design certification application under part 52 of this chapter is subject to the conditions in paragraphs (a), (b)(1), (b)(4), (c), (d), (e), (f)(3), and (g)(3) of this section.

* * * * *

(b)* * *

(1)* * *

(i) *Section III Materials.* When applying the 1992 Edition of Section III, applicants or licensees must apply the 1992 Edition with the 1992 Addenda of Section II of the ASME Boiler and Pressure Vessel Code.

(ii) *Weld leg dimensions.* When applying the 1989 Addenda through the latest edition, and addenda incorporated by reference in paragraph (b)(1) of this section, applicants or licensees may not apply paragraph NB—3683.4(c)(1), Footnote 11 to Figure NC—3673.2(b)—1, and Figure ND—3673.2(b)—1.

(iii) *Seismic design.* Applicants or licensees may use Articles NB—3200, NB—3600, NC—3600, and ND—3600 up to and including the 1993 Addenda, subject to the limitation specified in paragraph (b)(1)(ii) of this section. Applicants or licensees may not use these articles in the 1994 Addenda through the latest edition and addenda incorporated by reference in paragraph (b)(1) of this section.

* * * * *

(v) *Independence of inspection.* Applicants or licensees may not apply NCA—4134.10(a) of Section III, 1995 Edition, through the latest edition and addenda incorporated by reference in paragraph (b)(1) of this section.

* * * * *

(4) *Design, Fabrication, and Materials Code Cases.* Applicants or licensees may apply the ASME Boiler and Pressure Vessel Code cases listed in NRC Regulatory Guide 1.84, Revision 32, without prior NRC approval subject to the following:

* * * * *

(d)* * *

(1) For a nuclear power plant whose application for a construction permit under this part, or a combined license or manufacturing license under part 52 of this chapter is docketed after May 14, 1984, or for an application for a standard design approval or a standard design

certification docketed after May 14, 1984, components classified Quality Group B⁹ must meet the requirements for Class 2 Components in Section III of the ASME Boiler and Pressure Vessel Code.

* * * * *

(e)* * *

(1) For a nuclear power plant whose application for a construction permit under this part, or a combined license or manufacturing license under part 52 of this chapter is docketed after May 14, 1984, or for an application for a standard design approval or a standard design certification docketed after May 14, 1984, components classified Quality Group C⁹ must meet the requirements for Class 3 components in Section III of the ASME Boiler and Pressure Vessel Code.

* * * * *

(f)* * *

(3) For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part or design approval, design certification, combined license, or manufacturing license under part 52 of this chapter, was issued on or after July 1, 1974:

* * * * *

(iii)(A) Pumps and valves, in facilities whose construction permit under this part, or design certification or design approval under part 52 of this chapter was issued before November 22, 1999, which are classified as ASME Code Class 1 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in the editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this

⁹See footnotes at end of section.

section (or the optional ASME Code cases that are listed in NRC Regulatory Guide 1.147, through Revision 13, that are incorporated by reference in paragraph (b) of this section) applied to the construction of the particular pump or valve or the summer 1973 Addenda, whichever is later.

(B) Pumps and valves, in facilities whose construction permit under this part, or design certification, design approval, combined license, or manufacturing license under part 52 of this chapter, is issued on or after November 22, 1999, which are classified as ASME Code Class 1 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in editions and addenda of the ASME OM Code (or the optional ASME Code cases listed in the NRC Regulatory Guide 1.192 that is incorporated by reference in paragraph (b) of this section) referenced in paragraph (b)(3) of this section at the time the construction permit is issued.

(iv)* * *

(B) Pumps and valves, in facilities whose construction permit under this part or design certification or combined license under part 52 of this chapter is issued on or after November 22, 1999, which are classified as ASME Code Class 2 and 3 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in editions and addenda of the ASME OM Code (or the optional ASME Code cases listed in the NRC Regulatory Guide 1.192 that is incorporated by reference in paragraph (b) of this section) referenced in paragraph (b)(3) of this section at the time the construction permit is issued.

* * * * *

(4)* * *

(i) Inservice tests to verify operational readiness of pumps and valves, whose function is required for safety, conducted during the initial 120-month interval must comply with the

requirements in the latest edition and addenda of the Code incorporated by reference in paragraph (b) of this section on the date 12 months before the date of issuance of the operating license under this part, or 12 months before the date scheduled for initial loading fuel under a combined license under part 52 of this chapter (or the optional ASME Code cases listed in NRC Regulatory Guide 1.192, that is incorporated by reference in paragraph (b) of this section), subject to the limitations and modifications listed in paragraph (b) of this section.

* * * * *

(g) * * *

(3) For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part, or design certification, design approval, combined license, or manufacturing license under part 52 of this chapter, was issued on or after July 1, 1974:

* * * * *

(4) * * *

(i) Inservice examinations of components and system pressure tests conducted during the initial 120-month inspection interval must comply with the requirements in the latest edition and addenda of the Code incorporated by reference in paragraph (b) of this section on the date 12 months before the date of issuance of the operating license under this part, or 12 months before the date scheduled for initial loading of fuel under a combined license under part 52 of this chapter (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 13, that are incorporated by reference in paragraph (b) of this section), subject to the limitations and modifications listed in paragraph (b) of this section.

* * * * *

(v) For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part or combined license under part 52 of this chapter was issued after January 1, 1956:

* * * * *

(h)* * *

(3) Safety systems. Applications filed on or after May 13, 1999, for construction permits and operating licenses under this part, and for design approvals, design certifications, and combined licenses under part 52 of this chapter, must meet the requirements for safety systems in IEEE Std. 603—1991 and the correction sheet dated January 30, 1995.

87. In § 50.59, paragraphs (b), (d)(2), and (d)(3) are revised to read as follows:

§ 50.59 Changes, tests, and experiments.

* * * * *

(b) This section applies to each holder of an operating license issued under this part or a combined license issued under part 52 of this chapter, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or § 50.110 or a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility.

* * * * *

(d)* * *

(2) The licensee shall submit, as specified in § 50.4 or § 52.3 of this chapter, as applicable, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For combined licenses, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a combined license to the date the Commission makes its findings under 10 CFR 52.103(g).

(3) The records of changes in the facility must be maintained until the termination of an operating license issued under this part, a combined license issued under part 52 of this chapter, or the termination of a license issued under 10 CFR part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.

88. In § 50.61, paragraph (b)(1) is revised to read as follows:

§ 50.61 Fracture toughness requirements for protection against pressurized thermal shock events.

* * * * *

(b)* * *

(1) For each pressurized water nuclear power reactor for which an operating license has been issued under this part or a combined license has been issued under part 52 of this chapter, other than a nuclear power reactor facility for which the certifications required under § 50.82(a)(1) have been submitted, the licensee shall have projected values of RT_{PTS} , accepted by the NRC, for each reactor vessel beltline material for the EOL fluence of the material. The assessment of RT_{PTS} must use the calculation procedures given in paragraph (c)(1) of this section, except as provided in paragraphs (c)(2) and (c)(3) of this section. The assessment must specify the bases for the projected value of RT_{PTS} for each vessel beltline material, including the assumptions regarding core loading patterns, and must specify the copper and nickel contents and the fluence value used in the calculation for each beltline material. This

assessment must be updated whenever there is a significant² change in projected values of RT_{PTS} , or upon request for a change in the expiration date for operation of the facility.

* * * * *

89. In § 50.62, paragraph (d) is revised to read as follows:

§ 50.62 Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.

* * * * *

(d) *Implementation.* For each light-water-cooled nuclear power plant operating license issued before [INSERT EFFECTIVE DATE OF FINAL RULE], by 180 days after the issuance of the QA guidance for non-safety related components, each licensee shall develop and submit to the Commission, as specified in § 50.4, a proposed schedule for meeting the requirements of paragraphs (c)(1) through (c)(5) of this section. Each shall include an explanation of the schedule along with a justification if the schedule calls for final implementation later than the second refueling outage after July 26, 1984, or the date of issuance of a license authorizing operation above 5 percent of full power. A final schedule shall then be mutually agreed upon by the Commission and licensee. For each light-water-cooled nuclear power plant operating license application submitted after [INSERT EFFECTIVE DATE OF FINAL RULE], the applicant shall submit information in its final safety analysis report demonstrating how it will comply with paragraphs (c)(1) through (c)(5) of this section.

²Changes to RT_{PTS} values are considered significant if either the previous value or the current value, or both values, exceed the screening criterion before the expiration of the operating license or the combined license under part 52 of this chapter, including any renewed term, if applicable for the plant.

90. In § 50.63, the introductory text of paragraphs (a)(1) and (c)(1) are revised to read as follows:

§ 50.63 Loss of all alternating current power.

(a)* * *

(1) Each light-water-cooled nuclear power plant licensed to operate under this part, each light-water-cooled nuclear power plant licensed under subpart C of 10 CFR part 52 after the Commission makes the finding under § 52.103(g) of this chapter, and each design for a light-water-cooled nuclear power plant approved under a standard design approval, standard design certification, and manufacturing license under part 52 of this chapter must be able to withstand for a specified duration and recover from a station blackout as defined in § 50.2. The specified station blackout duration shall be based on the following factors:

* * * * *

(c)* * *

(1) *Information Submittal.* For each light-water-cooled nuclear power plant licensed to operate on or before *July 21, 1988*, the licensee shall submit the information defined below to the Director of the Office of Nuclear Reactor Regulation by *April 17, 1989*. For each light-water-cooled nuclear power plant licensed to operate after *July 21, 1988*, but before [INSERT EFFECTIVE DATE OF FINAL RULE], the licensee shall submit the information defined below to the Director of the Office of Nuclear Reactor Regulation, by 270 days after the date of license issuance. For each light-water-cooled nuclear power plant operating license application submitted after [INSERT EFFECTIVE DATE OF FINAL RULE], the applicant shall submit the information defined below in its final safety analysis report.

* * * * *

91. In § 50.65, paragraph (a)(1) is revised to read as follows:

§ 50.65 Requirements for monitoring the effectiveness of maintenance at nuclear power plants.

* * * * *

(a)(1) Each holder of an operating license for a nuclear power plant under this part and each holder of a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall monitor the performance or condition of structures, systems, or components, against licensee-established goals, in a manner sufficient to provide reasonable assurance that these structures, systems, and components, as defined in paragraph (b) of this section, are capable of fulfilling their intended functions. These goals shall be established commensurate with safety and, where practical, take into account industry-wide operating experience. When the performance or condition of a structure, system, or component does not meet established goals, appropriate corrective action shall be taken. For a nuclear power plant for which the licensee has submitted the certifications specified in § 50.82(a)(1) or 52.110(a)(1) of this chapter, as applicable, this section shall only apply to the extent that the licensee shall monitor the performance or condition of all structures, systems, or components associated with the storage, control, and maintenance of spent fuel in a safe condition, in a manner sufficient to provide reasonable assurance that these structures, systems, and components are capable of fulfilling their intended functions.

* * * * *

92. In § 50.70 paragraphs (a) and (b)(2) are revised to read as follows:

§ 50.70 Inspections.

(a) Each applicant for or holder of a license, including a construction permit or an early site permit, shall permit inspection, by duly authorized representatives of the Commission, of his

records, premises, activities, and of licensed materials in possession or use, related to the license or construction permit or early site permit as may be necessary to effectuate the purposes of the Act, as amended, including Section 105 of the Act, and the Energy Reorganization Act of 1974, as amended.

(b)* * *

(2) For a site with a single power reactor or fuel facility licensed under part 50 or part 52 of this chapter, or a facility issued a manufacturing license under part 52, the space provided shall be adequate to accommodate a full-time inspector, a part-time secretary and transient NRC personnel and will be generally commensurate with other office facilities at the site. A space of 250 square feet either within the site's office complex or in an office trailer or other onsite space is suggested as a guide. For sites containing multiple power reactor units or fuel facilities, additional space may be requested to accommodate additional full-time inspector(s). The office space that is provided shall be subject to the approval of the Director, Office of New Reactors, or the Director, Office of Nuclear Reactor Regulation. All furniture, supplies and communication equipment will be furnished by the Commission.

* * * * *

93. In § 50.71, paragraphs (a), (c), (d)(1), and the introductory text of paragraph (e) are revised, paragraph (f) is redesignated as paragraph (g) and revised, and new paragraph (f) is added to read as follows:

§ 50.71 Maintenance of records, making of reports.

(a) Each licensee, including each holder of a construction permit or early site permit, shall maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations, and orders of the Commission in effectuating the purposes of the Act, including Section 105 of the Act, and the

Energy Reorganization Act of 1974, as amended. Reports must be submitted in accordance with § 50.4 or 10 CFR 52.3, as applicable.

* * * * *

(c) Records that are required by the regulations in this part or part 52 of this chapter, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license or, in the case of an early site permit, until the permit expires.

(d)(1) Records which must be maintained under this part or part 52 of this chapter may be the original or a reproduced copy or microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with, and loss of records.

* * * * *

(e) Each person licensed to operate a nuclear power reactor under the provisions of § 50.21 or § 50.22 shall update periodically, as provided in paragraphs (e) (3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the license, to assure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the original FSAR, or as appropriate, the last

update to the FSAR under this section. The submittal shall include the effects¹ of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) or, in the case of a license that references a certified design, in accordance with § 52.98(c) of this chapter; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

* * * * *

(f) Each person licensed to manufacture a nuclear power reactor under subpart F of 10 CFR part 52 shall update the FSAR originally submitted as part of the application to reflect any modification to the design that is approved by the Commission under § 52.171 of this chapter, and any new analyses of the design performed by or on behalf of the licensee at the NRC's request. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee with respect to the modification approved under § 52.171 of this chapter or the analyses requested by the Commission under § 52.171 of this chapter. The updated information shall be appropriately located within the update to the FSAR.

(g) The provisions of this section apply to nuclear power reactor licensees that have submitted the certification of permanent cessation of operations required under §§ 50.82(a)(1)(i) or 52.110(a)(1) of this chapter. The provisions of paragraphs (a), (c), and (d) of this section also apply to non-power reactor licensees that are no longer authorized to operate.

¹Effects of changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

94. In § 50.72, the introductory text of paragraph (a)(1) is revised to read as follows:

§ 50.72 Immediate notification requirements for operating nuclear power reactors.

(a)* * *

(1) Each nuclear power reactor licensee licensed under §§ 50.21(b) or 50.22 holding an operating license under this part or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g), shall notify the NRC Operations Center via the Emergency Notification System of:

* * * * *

95. In § 50.73, paragraph (a)(1) is revised to read as follows:

§ 50.73 Licensee event report system.

(a)* * *

(1) The holder of an operating license under this part or a combined license under part 52 of this chapter (after the Commission has made the finding under § 52.103(g) of this chapter) for a nuclear power plant (licensee) shall submit a Licensee Event Report (LER) for any event of the type described in this paragraph within 60 days after the discovery of the event. In the case of an invalid actuation reported under §50.73(a)(2)(iv), other than actuation of the reactor protection system (RPS) when the reactor is critical, the licensee may, at its option, provide a telephone notification to the NRC Operations Center within 60 days after discovery of the event instead of submitting a written LER. Unless otherwise specified in this section, the licensee shall report an event if it occurred within 3 years of the date of discovery regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

* * * * *

96. In § 50.75, paragraphs (a) and (b) are revised, paragraphs (f)(1), (f)(2), (f)(3), and (f)(4) are redesignated as paragraphs (f)(2), (f)(3), (f)(4), and (f)(5), respectively, and paragraphs (e)(3) and (f)(1) are added to read as follows:

§ 50.75 Reporting and recordkeeping for decommissioning planning.

(a) This section establishes requirements for indicating to NRC how a licensee will provide reasonable assurance that funds will be available for the decommissioning process. For power reactor licensees (except a holder of a manufacturing license under part 52 of this chapter), reasonable assurance consists of a series of steps as provided in paragraphs (b), (c), (e), and (f) of this section. Funding for the decommissioning of power reactors may also be subject to the regulation of Federal or State Government agencies (e.g., Federal Energy Regulatory Commission (FERC) and State Public Utility Commissions) that have jurisdiction over rate regulation. The requirements of this section, in particular paragraph (c) of this section, are in addition to, and not substitution for, other requirements, and are not intended to be used by themselves or by other agencies to establish rates.

(b) Each power reactor applicant for or holder of an operating license, and each applicant for a combined license under subpart C of 10 CFR part 52 for a production or utilization facility of the type and power level specified in paragraph (c) of this section shall submit a decommissioning report, as required by § 50.33(k).

(1) For an applicant for or holder of an operating license under part 50, the report must contain a certification that financial assurance for decommissioning will be (for a license applicant), or has been (for a license holder), provided in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section. For an applicant for a combined license under subpart C of 10 CFR part 52, the report must contain a certification that

financial assurance for decommissioning will be provided no later than 30 days after the Commission publishes notice in the *Federal Register* under § 52.103(a) in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section, adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section.

(2) The amount to be provided must be adjusted annually using a rate at least equal to that stated in paragraph (c)(2) of this section.

(3) The amount must be covered by one or more of the methods described in paragraph (e) of this section as acceptable to the NRC.

(4) The amount stated in the applicant's or licensee's certification may be based on a cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC; *provided, however*, that an applicant for or holder of a combined license need not obtain such financial instrument or submit a copy to the Commission except as provided in paragraph (e)(3) of this section.

* * * * *

(e)* * *

(3) Each holder of a combined license under subpart C of 10 CFR part 52 shall, 2 years before and 1 year before the scheduled date for initial loading of fuel under § 52.103, submit a report to the NRC containing a certification updating the information described under paragraph (b)(1) of this section, including a copy of the financial instrument to be used. No later than 30 days after the Commission publishes notice in the *Federal Register* under 10 CFR 52.103(a), the licensee shall submit a report containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification, including a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.

(f)(1) Each power reactor licensee shall report, on a calendar-year basis, to the NRC by March 31, 1999, and at least once every 2 years on the status of its decommissioning funding for each reactor or part of a reactor that it owns. However, each holder of a combined license under part 52 of this chapter need not begin reporting until the date that the Commission has made the finding under § 52.103(g) of this chapter. The information in this report must include, at a minimum the amount of decommissioning funds estimated to be required under 10 CFR 50.75(b) and (c); the amount accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying under paragraph (e)(1)(v) of this section; any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed so that it will close within 5 years (before the end of its licensed life), or has already closed (before the end of its licensed life), or for plants involved in mergers or acquisitions shall submit this report annually.

* * * * *

97. Section 50.78 is revised to read as follows:

§ 50.78 Installation information and verification.

Each holder of a construction permit and each holder of a combined license shall, if requested by the Commission, submit installation information on Form-71, permit verification thereof by the International Atomic Energy Agency, and take other action as may be necessary to implement the US/IAEA Safeguards Agreement, in the manner set forth in § 75.6 and §§ 75.11 through 75.14 of this chapter.

98. In § 50.80, paragraphs (a) and (b) are revised to read as follows:

§ 50.80 Transfer of licenses.

(a) No license for a production or utilization facility (including, but not limited to, permits under this part and part 52 of this chapter, and licenses under parts 50 and 52 of this chapter), or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.

(b)(1) An application for transfer of a license shall include:

(i) For a construction permit or operating license under this part, as much of the information described in §§ 50.33 and 50.34 of this part with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

(ii) For an early site permit under part 52 of this chapter, as much of the information described in §§ 52.16 and 52.17 of this chapter with respect to the identity and technical qualifications of the proposed transferee as would be required by those sections if the application were for an initial license.

(iii) For a combined license under part 52 of this chapter, as much of the information described in §§ 52.77 and 52.79 of this chapter with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

(iv) For a manufacturing license under part 52 of this chapter, as much of the information described in §§ 52.156 and 52.157 of this chapter with respect to the identity and technical qualifications of the proposed transferee as would be required by those sections if the application were for an initial license.

(2) The application shall include also a statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement to limit access to Restricted Data pursuant to § 50.37. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility or site involved.

* * * * *

99. In § 50.81, paragraph (d)(1) is revised, and a new paragraph (d)(3) is added to read as follows:

§ 50.81 Creditor regulations.

(d)* * *

(1) *License* includes any license under this chapter, any construction permit under this part, and any early site permit under part 52 of this chapter, which may be issued by the Commission with regard to a facility;

* * * * *

(3) *Facility* includes but is not limited to, a site which is the subject of an early site permit under subpart A of part 52 of this chapter, and a reactor manufactured under a manufacturing license under subpart F of part 52 of this chapter.

100. Section 50.90 is revised to read as follows:

§ 50.90 Application for amendment of license, construction permit, or early site permit.

Whenever a holder of a license, including a construction permit and operating license under this part, and an early site permit, combined license, and manufacturing license under part 52 of this chapter, desires to amend the license or permit, application for an amendment must be filed with the Commission, as specified in §§ 50.4 or 52.3 of this chapter, as applicable, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.

101. In § 50.91, the introductory text is revised to read as follows:

§ 50.91 Notice for public comment; State consultation.

The Commission will use the following procedures for an application requesting an amendment to an operating license under this part or a combined licensed under part 52 of this chapter for a facility licensed under §§ 50.21(b) or 50.22, or for a testing facility, except for amendments subject to hearings governed by 10 CFR part 2, subpart L. For amendments subject to 10 CFR part 2, subpart L, the following procedures will apply only to the extent specifically referenced in § 2.309(b) of this chapter, except that notice of opportunity for hearing must be published in the *Federal Register* at least 30 days before the requested amendment is issued by the Commission:

* * * * *

102. Section 50.92 paragraph (a), and the introductory text of paragraph (c) are revised to read as follows:

§ 50.92 Issuance of amendment.

(a) In determining whether an amendment to a license, construction permit, or early site permit will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses, construction permits, or early site permits to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a construction permit will be issued before the issuance of the amendment to the license, provided however, that if the application involves a material alteration to a nuclear power reactor manufactured under part 52 of this chapter before its installation at a site, or a combined license before the date that the Commission makes the finding under § 52.103(g) of this chapter, no application for a construction permit is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action:

- (1) Under § 2.105 of this chapter before acting thereon; and
- (2) As soon as practicable after the application has been docketed.

* * * * *

(c) The Commission may make a final determination, under the procedures in § 50.91, that a proposed amendment to an operating license or a combined license for a facility or reactor licensed under §§ 50.21(b) or 50.22, or for a testing facility involves no significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:

* * * * *

103. Section 50.100 is revised to read as follows:

§ 50.100 Revocation, suspension, modification of licenses, permits, and approvals for cause.

A license, permit, or standard design approval under parts 50 or 52 of this chapter may be revoked, suspended, or modified, in whole or in part, for any material false statement in the

application or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license, permit, or approval on an original application (other than those relating to §§ 50.51, 50.42(a), and 50.43(b)); or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the permit or license, *provided, however*, that failure to make timely completion of the proposed construction or alteration of a facility under a construction permit under part 50 of this chapter or a combined license under part 52 of this chapter shall be governed by the provisions of § 50.55(b); or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, permit, approval, or order of the Commission.

104. In § 50.109, paragraph (a)(1) is revised to read as follows:

§ 50.109 Backfitting.

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after:

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985;

(ii) Six (6) months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985;

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses;

(iv) The date of issuance of the design approval under subpart E of part 52 of this chapter;

(v) The date of issuance of a manufacturing license under subpart F of part 52 of this chapter;

(vi) The date of issuance of the first construction permit issued for a duplicate design under appendix N of this part; or

(vii) The date of issuance of a combined license under subpart C of part 52 of this chapter, provided that if the combined license references an early site permit, the provisions in § 52.39 of this chapter apply with respect to the site characteristics, design parameters, and terms and conditions specified in the early site permit. If the combined license references a standard design certification rule under subpart B of 10 CFR part 52, the provisions in § 52.63 of this chapter apply with respect to the design matters resolved in the standard design certification rule, *provided however*, that if any specific backfitting limitations are included in a referenced design certification rule, those limitations shall govern. If the combined license references a standard design approval under subpart E of 10 CFR part 52, the provisions in § 52.145 of this chapter apply with respect to the design matters resolved in the standard design approval. If the combined license uses a reactor manufactured under a manufacturing license under subpart F of 10 CFR part 52, the provisions of § 52.171 of this chapter apply with respect to matters resolved in the manufacturing license proceeding.

* * * * *

105. Section 50.120 is revised to read as follows:

§ 50.120 Training and qualification of nuclear power plant personnel.

(a) *Applicability.* The requirements of this section apply to each applicant for and each holder of an operating license issued under this part and each holder of a combined license issued under part 52 of this chapter for a nuclear power plant of the type specified in § 50.21(b) or § 50.22.

(b) *Requirements.* (1)(i) Each nuclear power plant operating license applicant, by 18 months prior to fuel load, and each holder of an operating license shall establish, implement, and maintain a training program that meets the requirements of paragraphs (b)(2) and (b)(3) of this section.

(ii) Each holder of a combined license shall establish, implement, and maintain the training program that meets the requirements of paragraphs (b)(2) and (b)(3) of this section, as described in the final safety analysis report no later than 18 months before the scheduled date for initial loading of fuel.

(2) The training program must be derived from a systems approach to training as defined in 10 CFR 55.4, and must provide for the training and qualification of the following categories of nuclear power plant personnel:

- (i) Non-licensed operator.
- (ii) Shift supervisor.
- (iii) Shift technical advisor.
- (iv) Instrument and control technician.
- (v) Electrical maintenance personnel.
- (vi) Mechanical maintenance personnel.
- (vii) Radiological protection technician.
- (viii) Chemistry technician.
- (ix) Engineering support personnel.

(3) The training program must incorporate the instructional requirements necessary to provide qualified personnel to operate and maintain the facility in a safe manner in all modes of operation. The training program must be developed to be in compliance with the facility license, including all technical specifications and applicable regulations. The training program must be periodically evaluated and revised as appropriate to reflect industry experience as well as changes to the facility, procedures, regulations, and quality assurance requirements. The training program must be periodically reviewed by licensee management for effectiveness. Sufficient records must be maintained by the licensee to maintain program integrity and kept available for NRC inspection to verify the adequacy of the program.

106. In Appendix A to Part 50, the first paragraph under the introduction and the second paragraph under Criterion 19 are revised to read as follows:

**APPENDIX A TO PART 50 - GENERAL DESIGN CRITERIA FOR NUCLEAR POWER
PLANTS**

* * * * *

Introduction

Under the provisions of § 50.34, an application for a construction permit must include the principal design criteria for a proposed facility. Under the provisions of 10 CFR 52.47, 52.79, 52.137, and 52.157, an application for a design certification, combined license, design approval, or manufacturing license, respectively, must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.

* * * * *

Criterion 19 - Control Room.

* * * * *

Applicants for and holders of construction permits and operating licenses under this part who apply on or after January 10, 1997, applicants for design approvals or certifications under part 52 of this chapter who apply on or after January 10, 1997, applicants for and holders of combined licenses or manufacturing licenses under part 52 of this chapter who do not reference a standard design approval or certification, or holders of operating licenses using an alternative source term under § 50.67, shall meet the requirements of this criterion, except that with regard to control room access and occupancy, adequate radiation protection shall be provided to ensure that radiation exposures shall not exceed 0.05 Sv (5 rem) total effective dose equivalent (TEDE) as defined in § 50.2 for the duration of the accident.

* * * * *

107. In Appendix B to Part 50, the Introduction and Section I are revised to read as follows:

APPENDIX B TO PART 50—QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANTS AND FUEL REPROCESSING PLANTS

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Every applicant for a combined license under part 52 of this chapter is required by the provisions of § 52.79 of this chapter to

include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation. For applications submitted after **[INSERT DATE OF FINAL RULE]**, every applicant for an early site permit under part 52 of this chapter is required by the provisions of § 52.17 of this chapter to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval or design certification under part 52 of this chapter is required by the provisions of 10 CFR 52.137 and 52.47, respectively, to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a manufacturing license under part 52 of this chapter is required by the provisions of 10 CFR 52.157 to include in its final safety analysis report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this appendix, “quality assurance” comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

I. Organization

The applicant¹ shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. These persons and organizations performing quality assurance functions shall report

¹While the term “applicant” is used in these criteria, the requirements are, of course, applicable after such a person has received a license to construct and operate a nuclear power plant or a fuel reprocessing plant or has received an early site permit, design approval, design certification, or manufacturing license, as applicable. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits, operating licenses, early site permits, design approvals, combined licenses, and manufacturing licenses.

to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being performed, shall have direct access to the levels of management necessary to perform this function.

* * * * *

108. In Appendix C to Part 50, the heading, the first paragraph of General Information, and the headings of Sections I.A and II.A, and Section III are revised to read as follows:

**APPENDIX C TO PART 50 — A GUIDE FOR THE FINANCIAL DATA AND RELATED
INFORMATION REQUIRED TO ESTABLISH FINANCIAL QUALIFICATIONS FOR
CONSTRUCTION PERMITS AND COMBINED LICENSES**

General Information

This appendix is intended to appraise applicants for construction permits and combined licenses for production or utilization facilities of the types described in § 50.21(b) or § 50.22, or testing facilities, of the general kinds of financial data and other related information that will demonstrate the financial qualification of the applicant to carry out the activities for which the permit or license is sought. The kind and depth of information described in this guide is not

intended to be a rigid and absolute requirement. In some instances, additional pertinent material may be needed. In any case, the applicant should include information other than that specified, if the information is pertinent to establishing the applicant's financial ability to carry out the activities for which the permit or license is sought.

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I. * * *

A. *Applications for construction permits or combined licenses*

* * * * *

II. * * *

A. *Applications for construction permits or combined licenses*

* * * * *

III. ANNUAL FINANCIAL STATEMENT

Each holder of a construction permit for a production or utilization facility of a type described in § 50.21(b) or § 50.22 or a testing facility, and each holder of a combined license issued under part 52 of this chapter, is required by § 50.71(b) to file its annual financial report with the Commission at the time of issuance. This requirement does not apply to licensees or holders of construction permits for medical and research reactors.

* * * * *

109. In Appendix E to Part 50, Sections I, III, IV.F.2.a, IV.F.2.c, and V are revised, and footnotes 6, 7, 8, 9, and 10 are redesignated as 7, 8, 9, 10, and 11, respectively, and a new footnote 6 is added to read as follows:

**APPENDIX E TO PART 50—EMERGENCY PLANNING AND PREPAREDNESS FOR
PRODUCTION AND UTILIZATION FACILITIES**

* * * * *

I. Introduction

Each applicant for a construction permit is required by § 50.34(a) to include in the preliminary safety analysis report a discussion of preliminary plans for coping with emergencies. Each applicant for an operating license is required by § 50.34(b) to include in the final safety analysis report plans for coping with emergencies. Each applicant for a combined license under subpart C of part 52 of this chapter is required by § 52.79 of this chapter to include in the application plans for coping with emergencies. Each applicant for an early site permit under subpart A of part 52 of this chapter may submit plans for coping with emergencies under § 52.17 of this chapter.

This appendix establishes minimum requirements for emergency plans for use in attaining an acceptable state of emergency preparedness. These plans shall be described generally in the preliminary safety analysis report for a construction permit and submitted as part of the final safety analysis report for an operating license. These plans, or major features thereof, may be submitted as part of the site safety analysis report for an early site permit.

* * * * *

III. The Final Safety Analysis Report; Site Safety Analysis Report

The final safety analysis report or the site safety analysis report for an early site permit that includes complete and integrated emergency plans under § 52.17(b)(2)(ii) of this chapter shall contain the plans for coping with emergencies. The plans shall be an expression of the overall concept of operation; they shall describe the essential elements of advance planning that have been considered and the provisions that have been made to cope with emergency situations. The plans shall incorporate information about the emergency response roles of supporting organizations and offsite agencies. That information shall be sufficient to provide assurance of coordination among the supporting groups and with the licensee. The site safety

analysis report for an early site permit which proposes major features must address the relevant provisions of 10 CFR 50.47 and 10 CFR part 50, appendix E, within the scope of emergency preparedness matters addressed in the major features.

The plans submitted must include a description of the elements set out in Section IV for the emergency planning zones (EPZs) to an extent sufficient to demonstrate that the plans provide reasonable assurance that adequate protective measures can and will be taken in the event of an emergency.

IV. Content of Emergency Plans

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a. A full participation⁴ exercise which tests as much of the licensee, State, and local emergency plans as is reasonably achievable without mandatory public participation shall be conducted for each site at which a power reactor is located.

(i) For an operating license issued under this part, this exercise must be conducted within two years before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated power) of the first reactor and shall include participation by each State and local government within the plume exposure pathway EPZ and each state within the ingestion exposure pathway EPZ. If the full participation exercise is conducted more than one year prior to issuance of an operating licensee for full power, an exercise which tests the licensee's onsite emergency plans must be conducted within one year before issuance of an

⁴Full participation when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite local and State authorities and licensee personnel physically and actively take part in testing their integrated capability to adequately assess and respond to an accident at a commercial nuclear power plant. Full participation includes testing major observable portions of the onsite and offsite emergency plans and mobilization of State, local and licensee personnel and other resources in sufficient numbers to verify the capability to respond to the accident scenario.

operating license for full power. This exercise need not have State or local government participation.

(ii) For a combined license issued under part 52 of this chapter, this exercise must be conducted within two years of the scheduled date for initial loading of fuel. If the first full participation exercise is conducted more than one year before the scheduled date for initial loading of fuel, an exercise which tests the licensee's onsite emergency plans must be conducted within one year before the scheduled date for initial loading of fuel. This exercise need not have State or local government participation. If DHS identifies one or more deficiencies in the state of offsite emergency preparedness as the result of the first full participation exercise, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

(iii) For a combined licensee issued under part 52 of this chapter, if the applicant currently has an operating reactor at the site, an exercise, either full or partial participation,⁵ shall be conducted for each subsequent reactor constructed on the site. This exercise may be incorporated in the exercise requirements of Sections IV.F.2.b. and c. in this appendix. If DHS identifies one or more deficiencies in the state of offsite emergency preparedness as the result of this exercise for the new reactor, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

* * * * *

⁵Partial participation when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite authorities shall actively take part in the exercise sufficient to test direction and control functions; i.e., (a) protective action decision making related to emergency action levels, and (b) communication capabilities among affected State and local authorities and the licensee.

c. Offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the radiological response plan. Where the offsite authority has a role under a radiological response plan for more than one site, it shall fully participate in one exercise every two years and shall, at least, partially participate in other offsite plan exercises in this period. If two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the elements defining co-located licensees,⁶ each licensee shall:

- (1) Conduct an exercise biennially of its onsite emergency plan; and
- (2) Participate quadrennially in an offsite biennial full or partial participation exercise;

and

(3) Conduct emergency preparedness activities and interactions in the years between its participation in the offsite full or partial participation exercise with offsite authorities, to test and maintain interface among the affected State and local authorities and the licensee. Co-located licensees shall also participate in emergency preparedness activities and interaction with offsite authorities for the period between exercises.

* * * * *

V. Implementing Procedures

No less than 180 days before the scheduled issuance of an operating license for a nuclear power reactor or a license to possess nuclear material, or the scheduled date for initial loading of fuel for a combined license under part 52 of this chapter, the applicant's or licensee's detailed implementing procedures for its emergency plan shall be submitted to the Commission

⁶Co-located licensees are two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the following emergency planning and siting elements:

- a. plume exposure and ingestion emergency planning zones;
- b. offsite governmental authorities;
- c. offsite emergency response organizations;
- d. public notification system; and/or
- e. emergency facilities.

as specified in § 50.4. Licensees who are authorized to operate a nuclear power facility shall submit any changes to the emergency plan or procedures to the Commission, as specified in § 50.4, within 30 days of such changes.

* * * * *

110. In Appendix I to Part 50, the first paragraphs of Sections I, II, IV, and V are revised to read as follows:

**APPENDIX I TO PART 50—NUMERICAL GUIDES FOR DESIGN OBJECTIVES AND
LIMITING CONDITIONS FOR OPERATION TO MEET THE CRITERION “AS LOW AS IS
REASONABLY ACHIEVABLE” FOR RADIOACTIVE MATERIAL IN LIGHT-WATER-COOLED
NUCLEAR POWER REACTOR EFFLUENTS**

SECTION I. *Introduction.* Section 50.34a provides that an application for a construction permit shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal conditions, including expected occurrences. In the case of an application filed on or after January 2, 1971, the application must also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as practicable. Sections 52.47, 52.79, 52.137, and 52.157 of this chapter provide that applications for design certification, combined license, design approval, or manufacturing license, respectively, shall include a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems.

* * * * *

SECTION II. *Guides on design objectives for light-water-cooled nuclear power reactors licensed under 10 CFR part 50 or part 52* of this chapter. The guides on design objectives set

forth in this section may be used by an applicant for a construction permit as guidance in meeting the requirements of §50.34a(a), or by an applicant for a combined license under part 52 of this chapter as guidance in meeting the requirements of § 50.34a(d), or by an applicant for a design approval, a design certification, or a manufacturing license as guidance in meeting the requirements of § 50.34a(e). The applicant shall provide reasonable assurance that the following design objectives will be met.

* * * * *

SECTION IV. *Guides on technical specifications for limiting conditions for operation for light-water-cooled nuclear power reactors licensed under 10 CFR part 50 or part 52 of this chapter.* The guides on limiting conditions for operation for light-water-cooled nuclear power reactors set forth below may be used by an applicant for an operating license under this part or a design certification or combined license under part 52 of this chapter, or a licensee who has submitted a certification of permanent cessation of operations under § 50.82(a)(1) or § 52.110 of this chapter as guidance in developing technical specifications under § 50.36a(a) to keep levels of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable.

* * * * *

SECTION V. *Effective dates.* A. The guides for limiting conditions for operation set forth in this appendix shall be applicable in any case in which an application was filed on or after January 2, 1971, for a construction permit for a light-water-cooled nuclear power reactor under this part, or a design certification, a combined license, or a manufacturing license for a light-water-cooled nuclear power reactor under part 52 of this chapter.

* * * * *

111. In Appendix J to Part 50 in Option A, Section I, and paragraph II.k are revised and in Option B, Section I, and paragraphs V.B.2 and 3 are revised to read as follows:

**APPENDIX J TO PART 50—PRIMARY REACTOR CONTAINMENT LEAKAGE TESTING
FOR WATER-COOLED REACTORS**

* * * * *

OPTION A—PRESCRIPTIVE REQUIREMENTS

* * * * *

I. Introduction

One of the conditions of all operating licenses under this part and combined licenses under part 52 of this chapter for water-cooled power reactors as specified in §50.54(o) is that primary reactor containments shall meet the containment leakage test requirements set forth in this appendix. These test requirements provide for preoperational and periodic verification by tests of the leak-tight integrity of the primary reactor containment, and systems and components which penetrate containment of water-cooled power reactors, and establish the acceptance criteria for these tests. The purposes of the tests are to assure that (a) leakage through the primary reactor containment and systems and components penetrating primary containment shall not exceed allowable leakage rate values as specified in the technical specifications or associated bases; and (b) periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment. These test requirements may also be used for guidance in establishing appropriate containment leakage test requirements in technical specifications or associated bases for other types of nuclear power reactors.

II.* * *

K. La (percent/24 hours) means the maximum allowable leakage rate at pressure Pa as specified for preoperational tests in the technical specifications or associated bases, and as specified for periodic tests in the operating license or combined license, including the technical specifications in any referenced design certification or manufactured reactor used at the facility.

* * * * *

OPTION B—PERFORMANCE-BASED REQUIREMENTS

* * * * *

I. Introduction

One of the conditions required of all operating licenses and combined licenses for light-water-cooled power reactors as specified in §50.54(o) is that primary reactor containments meet the leakage-rate test requirements in either Option A or B of this appendix. These test requirements ensure that (a) leakage through these containments or systems and components penetrating these containments does not exceed allowable leakage rates specified in the technical specifications; and (b) integrity of the containment structure is maintained during its service life. Option B of this appendix identifies the performance-based requirements and criteria for preoperational and subsequent periodic leakage-rate testing.³

* * * * *

V.* * *

B.* * *

2. A licensee or applicant for an operating license under this part or a combined license under part 52 of this chapter may adopt Option B, or parts thereof, as specified in Section V.A of this appendix, by submitting its implementation plan and request for revision to technical

³Specific guidance concerning a performance-based leakage-test program, acceptable leakage-rate test methods, procedures, and analyses that may be used to implement these requirements and criteria are provided in Regulatory Guide 1.163, "Performance-Based Containment Leak-Test Program."

specifications (see paragraph B.3 of this section) to the Director of the Office of Nuclear Reactor Regulation or the Director of the Office of New Reactors, as appropriate.

3. The regulatory guide or other implementation document used by a licensee or applicant for an operating license under this part or a combined license under part 52 of this chapter to develop a performance-based leakage-testing program must be included, by general reference, in the plant technical specifications. The submittal for technical specification revisions must contain justification, including supporting analyses, if the licensee chooses to deviate from methods approved by the Commission and endorsed in a regulatory guide.

* * * * *

APPENDIX M TO PART 50 [REMOVED AND RESERVED]

112. Appendix M to Part 50 is removed and reserved.

113. The title of appendix N to part 50 is revised to read as follows:

**APPENDIX N TO PART 50—STANDARDIZATION OF NUCLEAR POWER PLANT DESIGNS:
PERMITS TO CONSTRUCT AND LICENSES TO OPERATE NUCLEAR POWER REACTORS
OF IDENTICAL DESIGN AT MULTIPLE SITES**

APPENDIX O TO PART 50 [REMOVED AND RESERVED]

114. Appendix O to Part 50 is removed and reserved.

115. In Appendix S to Part 50, the first paragraph titled “General Information,” Section I(a), and Section III are revised to read as follows:

**APPENDIX S TO PART 50—EARTHQUAKE ENGINEERING CRITERIA FOR NUCLEAR
POWER PLANTS**

General Information

This appendix applies to applicants for a construction permit or operating license under part 50, or a design certification, combined license, design approval, or manufacturing license under part 52 of this chapter, on or after January 10, 1997. However, for either an operating license applicant or holder whose construction permit was issued before January 10, 1997, the earthquake engineering criteria in Section VI of appendix A to 10 CFR part 100 continue to apply. Paragraphs IV.a.1.i, IV.a.1.ii, IV.4.b, and IV.4.c of this appendix apply to applicants for an early site permit under part 52.

I. Introduction

(a) Each applicant for a construction permit, operating license, design certification, combined license, design approval, or manufacturing license is required by §§ 50.34(a)(12), 50.34(b)(10), or 10 CFR 52.47, 52.79, 52.137, or 52.157, and General Design Criterion 2 of appendix A to this part, to design nuclear power plant structures, systems, and components important to safety to withstand the effects of natural phenomena, such as earthquakes, without loss of capability to perform their safety functions. Also, as specified in § 50.54(ff), nuclear power plants that have implemented the earthquake engineering criteria described herein must shut down if the criteria in paragraph IV(a)(3) of this appendix are exceeded.

* * * * *

III. Definitions

As used in these criteria:

Combined license means a combined construction permit and operating license with conditions for a nuclear power facility issued under subpart C of part 52 of this chapter.

Design Approval means an NRC staff approval, issued under subpart E of part 52 of this chapter, of a final standard design for a nuclear power reactor of the type described in 10 CFR 50.22.

Design Certification means a Commission approval, issued under subpart B of part 52 of this chapter, of a standard design for a nuclear power facility.

Manufacturing license means a license, issued under subpart F of part 52 of this chapter, authorizing the manufacture of nuclear power reactors but not their installation into facilities located at the sites on which the facilities are to be operated.

Operating basis earthquake ground motion (OBE) is the vibratory ground motion for which those features of the nuclear power plant necessary for continued operation without undue risk to the health and safety of the public will remain functional. The operating basis earthquake ground motion is only associated with plant shutdown and inspection unless specifically selected by the applicant as a design input.

Response spectrum is a plot of the maximum responses (acceleration, velocity, or displacement) of idealized single-degree-of-freedom oscillators as a function of the natural frequencies of the oscillators for a given damping value. The response spectrum is calculated for a specified vibratory motion input at the oscillators' supports.

Safe-shutdown earthquake ground motion (SSE) is the vibratory ground motion for which certain structures, systems, and components must be designed to remain functional.

Structures, systems, and components required to withstand the effects of the safe-shutdown earthquake ground motion or surface deformation are those necessary to assure:

- (1) The integrity of the reactor coolant pressure boundary;
- (2) The capability to shut down the reactor and maintain it in a safe-shutdown condition;

or

(3) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guideline exposures of § 50.34(a)(1).

Surface deformation is distortion of geologic strata at or near the ground surface by the processes of folding or faulting as a result of various earth forces. Tectonic surface deformation is associated with earthquake processes.

* * * * *

**PART 51 - ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING
AND RELATED REGULATORY FUNCTIONS**

116. The authority citation for Part 51 continues to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2201, 2297f); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853-854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95-604, Title II, 92 Stat. 3033-3041; and sec. 193, Pub. L. 101-575, 104 Stat. 2835 (42 U.S.C. 2243). Sections 51.20, 51.30, 51.60, 51.80, and 51.97 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241, and sec. 148, Pub. L. 100-203, 101 Stat. 1330-223 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036-3038 (42 U.S.C. 2021) and under Nuclear Waste Policy Act of 1982, sec. 121, 96 Stat. 2228 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act of 1982, sec. 114(f), 96 Stat. 2216, as amended (42 U.S.C. 10134(f)).

117. In § 51.17, paragraph (b) is revised to read as follows:

§ 51.17 Information collection requirements; OMB approval.

* * * * *

(b) The approved information collection requirements in this part appear in §§ 51.6, 51.16, 51.41, 51.45, 51.50, 51.51, 51.52, 51.53, 51.54, 51.55, 51.58, 51.60, 51.61, 51.62, 51.66, 51.68, and 51.69.

118. In § 51.20, paragraph (b)(6) is removed and reserved, and paragraphs (b)(1) and (b)(2) are revised to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b)* * *

(1) Issuance of a limited work authorization or a permit to construct a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 of this chapter, or issuance of an early site permit under part 52 of this chapter.

(2) Issuance or renewal of a full power or design capacity license to operate a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 of this chapter, or a combined license under part 52 of this chapter, except as provided under § 51.75.

* * * * *

(6) **[Reserved]**

* * * * *

119. In § 51.22, the introductory text of paragraph (c)(3), paragraphs (c)(3)(i), (c)(9), the introductory text of paragraphs (c)(10) and (c)(12), and paragraph (c)(17) are revised, and paragraphs (c)(22) and (c)(23) are added to read as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c)* * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 39, 40, 50, 51, 52, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to-

(i) Procedures for filing and reviewing applications for licenses or construction permits or early site permits or other forms of permission or for amendments to or renewals of licenses or construction permits or early site permits or other forms of permission;

* * * * *

(9) Issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter, which changes a requirement with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter, or which changes an inspection or a surveillance requirement, provided that- -

(i) The amendment involves no significant hazards consideration;

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and

(iii) There is no significant increase in individual or cumulative occupational radiation exposure.

(10) Issuance of an amendment to a permit or license under parts 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 52, 60, 61, 63, 70, or part 72 of this chapter which—

* * * * *

(12) Issuance of an amendment to a license under parts 50, 52, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (*i.e.*, protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted under parts 50, 52, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

* * * * *

(17) Issuance of an amendment to a permit or license under parts 30, 40, 50, 52, or part 70 of this chapter which deletes any limiting condition of operation or monitoring requirement based on or applicable to any matter subject to the provisions of the Federal Water Pollution Control Act.

* * * * *

(22) Issuance of a standard design approval under part 52 of this chapter.

(23) The Commission finding for a combined license under § 52.103(g) of this chapter.

* * * * *

120. In § 51.23 paragraphs (b) and (c) are revised to read as follows:

§ 51.23 Temporary storage of spent fuel after cessation of reactor operation—generic determination of no significant environmental impact.

* * * * *

(b) Accordingly, as provided in §§ 51.30(b), 51.53, 51.61, 51.80(b), 51.95 and 51.97(a), and within the scope of the generic determination in paragraph (a) of this section, no discussion of any environmental impact of spent fuel storage in reactor facility storage pools or independent spent fuel storage installations (ISFSI) for the period following the term of the reactor operating license or amendment, reactor combined license or amendment, or initial ISFSI license or amendment for which application is made, is required in any environmental report, environmental impact statement, environmental assessment or other analysis prepared in connection with the issuance or amendment of an operating license for a nuclear power reactor under parts 50 and 54 of this chapter, or issuance or amendment of a combined license for a nuclear power reactor under parts 52 and 54 of this chapter, or the issuance of an initial license for storage of spent fuel at an ISFSI, or any amendment thereto.

(c) This section does not alter any requirements to consider the environmental impacts of spent fuel storage during the term of a reactor operating license or combined license, or a license for an ISFSI in a licensing proceeding.

121. In § 51.26, a new paragraph (d) is added to read as follows:

§ 51.26 Requirement to publish notice of intent and conduct scoping process.

(a)* * *

(d)(1) Whenever the appropriate NRC staff director determines that a supplement to an early site permit environmental impact statement will be prepared by NRC for a combined license referencing that early site permit, a notice of intent will be prepared as provided in § 51.27, and will be published in the *Federal Register* as provided in § 51.116. The NRC staff need not conduct a scoping process (see §§ 51.27, 51.28, and 51.29), *provided, however*, that if scoping is conducted, then the scoping must be directed at matters to be addressed in the supplement as described in § 51.92.

(2) The appropriate NRC staff director may prepare a notice of intent as provided in § 51.27 before determining whether a supplement to an early site permit environmental impact statement will be prepared by NRC or whether an environmental assessment with a finding of no new and significant information will be prepared by NRC for a combined license referencing that early site permit, and publish the notice in the *Federal Register* as provided in § 51.116. The NRC staff may conduct a scoping process (see §§ 51.27, 51.28, and 51.29), *provided, however*, that scoping must be directed at matters that may be addressed in a supplement as described in § 51.92.

122. In § 51.27, the introductory text of paragraph (a) is revised, and a new paragraph (b) is added to read as follows:

§ 51.27 Notice of intent.

(a) The notice of intent required by § 51.26(a) shall:

* * * * *

(b)(1) The notice of intent required by § 51.26(d)(1) shall:

(i) State that a supplement to an early site permit final environmental impact statement will be prepared for a combined license application in accordance with § 51.92;

(ii) Identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application;

(iii) Identify the environmental report prepared by the applicant under § 51.50(c), and information on where copies are available for public inspection;

(iv) Describe the matters to be addressed in the supplement to an early site permit final environmental impact statement;

(v) Describe any proposed scoping process that the NRC staff may conduct, including the role of participants, whether written comments will be accepted, the last date for submitting comments and where comments should be sent, whether a public scoping meeting will be held, the time and place of any scoping meeting or when the time and place of the meeting will be announced; and

(vi) State the name, address, and telephone number of an individual in NRC who can provide information about the proposed action, the scoping process, and the supplement to the early site permit environmental impact statement.

(2) The notice of intent allowed by § 51.26(d)(2) shall:

(i) State that a supplement to an early site permit final environmental impact statement may be prepared for a combined license application in accordance with § 51.92;

(ii) Identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application;

(iii) Identify the environmental report prepared by the applicant under § 51.50(c), and information on where copies are available for public inspection;

(iv) Describe the matters that may be addressed in a supplement to an early site permit final environmental impact statement;

(v) Describe any proposed scoping process that the NRC staff may conduct, including the role of participants, whether written comments will be accepted, the last date for submitting comments and where comments should be sent, whether a public scoping meeting will be held, the time and place of any scoping meeting or when the time and place of the meeting will be announced; and

(vi) State the name, address, and telephone number of an individual in NRC who can provide information about the proposed action, the scoping process, and a possible supplement to the early site permit environmental impact statement.

123. In § 51.29, the section heading and paragraph (a)(1) are revised to read as follows:

§ 51.29 Scoping-environmental impact statement and supplement to environmental impact statement.

(a)* * *

(1) Define the proposed action which is to be the subject of the statement or supplement. For environmental impact statements other than a supplement to an early site permit final environmental impact statement prepared for a combined license application, the provisions of 40 CFR 1502.4 will be used for this purpose. For a supplement to an early site permit final environmental impact statement prepared for a combined license application, the proposed action shall be as set forth in the relevant provisions of § 51.92(e).

* * * * *

124. In § 51.30, paragraph (a) is revised, and paragraphs (d), (e), and (f) are added to read as follows:

§ 51.30 Environmental assessment.

(a) An environmental assessment for proposed actions, other than those for a combined license referencing an early site permit under part 52 for which an environmental

assessment is required under § 51.75(e), a standard design certification under 10 CFR part 52, or a manufacturing license under part 52, shall identify the proposed action and include:

(1) A brief discussion of:

(i) The need for the proposed action;

(ii) Alternatives as required by Section 102(2)(E) of NEPA;

(iii) The environmental impacts of the proposed action and alternatives as appropriate;

and

(2) A list of agencies and persons consulted, and identification of sources used.

* * * * *

(d) An environmental assessment for a standard design certification under subpart B of part 52 of this chapter must identify the proposed action, and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives (SAMDA) and the bases for not incorporating SAMDA in the design certification. An environmental assessment for an amendment to a design certification will be limited to the consideration of whether the design change which is the subject of the proposed amendment renders a SAMDA previously rejected in the earlier environmental assessment to become cost beneficial, or results in the identification of new SAMDA, in which case the costs and benefits of new SAMDA and the bases for not incorporating new SAMDA in the design certification must be addressed.

(e) An environmental assessment required by § 51.75(e) for a combined license under subpart C of part 52 of this chapter referencing an early site permit with an EIS resolving all environmental issues must:

(1) Identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application;

(2) Reference the final environmental impact statement prepared for the early site permit;

(3) Include a discussion of the bases for the NRC's conclusion that there is no new and significant information with respect to the issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding; and

(4) List the agencies and persons consulted, and identify the sources used.

(f) An environmental assessment for a manufacturing license under subpart F of part 52 of this chapter must identify the proposed action, and will be limited to the consideration of the costs and benefits of SAMDAs and the bases for not incorporating SAMDAs in the manufacturing license. An environmental assessment for an amendment to a manufacturing license will be limited to consideration whether the design change which is the subject of the proposed amendment either renders a SAMDA previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new SAMDAs, in which case the costs and benefits of new SAMDAs and the bases for not incorporating new SAMDAs in the manufacturing license must be addressed. In either case, the environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

125. Section 51.31 is revised to read as follows:

§ 51.31 Determinations based on environmental assessment.

(a) *General.* Upon completion of an environmental assessment for proposed actions other than those involving a standard design certification or a manufacturing license under part 52 of this chapter, the appropriate NRC staff director will determine whether to prepare an environmental impact statement, a finding of no significant impact, or a finding of no new and significant information on the proposed action. As provided in § 51.33, a determination to

prepare a draft finding of no significant impact may be made. As provided in § 51.37, a draft finding of no new and significant information must be prepared and published for public comment.

(b) *Standard design certification.* (1) For actions involving the issuance or amendment of a standard design certification, the Commission shall prepare a draft environmental assessment for public comment as part of the proposed rule. The proposed rule must state that:

(i) The Commission has determined in § 51.32 that there is no significant environmental impact associated with the issuance of the standard design certification or its amendment, as applicable; and

(ii) Comments on the environmental assessment will be limited to the consideration of SAMDAs as required by § 51.30(d).

(2) The Commission will prepare a final environmental assessment following the close of the public comment period for the proposed standard design certification.

(c) *Manufacturing license.* (1) Upon completion of the environmental assessment for actions involving issuance or amendment of a manufacturing license (manufacturing license environmental assessment), the NRC's Director of Nuclear Reactor Regulation (staff director) will determine the costs and benefits of severe accident mitigation design alternatives (SAMDAs) and the bases for not incorporating SAMDAs in the design of the reactor to be manufactured under the manufacturing license. The NRC staff director may determine to prepare a draft environmental assessment.

(2) The manufacturing license environmental assessment must state that:

(i) The Commission has determined in § 51.32 that there is no significant environmental impact associated with the issuance of a manufacturing license or an amendment to a manufacturing license, as applicable;

(ii) The environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license; and

(iii) Comments on the environmental assessment will be limited to the consideration of SAMDAs as required by § 51.30(f).

(3) If the NRC staff director makes a determination to prepare and issue a draft environmental assessment for public review and comment before making a final determination on the manufacturing license application, the assessment will be marked, "Draft." The NRC notice of availability on the draft environmental assessment will include a request for comments which specifies where comments should be submitted and when the comment period expires. The notice will state that copies of the environmental assessment and any related environmental documents are available for public inspection and where inspections can be made. A copy of the final environmental assessment will be sent to the U.S. Environmental Protection Agency, the applicant, any party to a proceeding, each commenter, and any other Federal, State, and local agencies, and Indian tribes, State, regional, and metropolitan clearinghouses expressing an interest in the action. Additional copies will be made available in accordance with § 51.123.

(4) When a hearing is held under the regulations in part 2 of this chapter on the proposed issuance of the manufacturing license or amendment, the NRC staff director will prepare a final environmental assessment which may be subject to modification as a result of review and decision as appropriate to the nature and scope of the proceeding. The presiding officer will issue the final environmental assessment.

(5) Only a party admitted into the proceeding with respect to a contention on the environmental assessment, or an entity participating in the proceeding pursuant to § 2.315(c) of this chapter, may take a position and offer evidence on the matters within the scope of the environmental assessment.

126. In § 51.32, paragraph (b) is added to read as follows:

§ 51.32 Finding of no significant impact.

* * * * *

(b) The Commission finds that there is no significant environmental impact associated with the issuance of:

- (1) A standard design certification under subpart B of part 52 of this chapter;
- (2) An amendment to a design certification;
- (3) A manufacturing license under subpart F of part 52 of this chapter; or
- (4) An amendment to a manufacturing license.

127. A new subheading is added after § 51.35 to read as follows:

FINDING OF NO NEW AND SIGNIFICANT INFORMATION

128. A new § 51.36 is added to read as follows:

§ 51.36 Finding of no new and significant information.

A finding of no new and significant information required by § 51.75(e) for a combined license under subpart C of part 52 of this chapter referencing an early site permit must:

- (a) Identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application;
- (b) Reference the final environmental impact statement prepared for the early site permit;

(c) Include a discussion of the bases for the NRC's conclusion that there is no new and significant information with respect to the issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding;

(d) List the agencies and persons consulted, and identify the sources used;

(e) List any other related environmental documents; and

(f) State that the finding and any related environmental documents are available for public inspection and where the documents may be inspected.

129. A new § 51.37 is added to read as follows:

§ 51.37 Draft finding of no new and significant information.

(a) The appropriate NRC staff director will prepare and issue a draft finding of no new and significant information for public review and comment before making a final determination whether to prepare an environmental impact statement or a final finding of no new and significant information on the proposed action.

(b) A draft finding of no new and significant information will:

(1) be marked "Draft;"

(2) contain the information specified in § 51.36;

(3) be accompanied by or include a request for comments on the draft finding within 30 days, or such longer period as may be specified in the notice of the draft finding; and

(4) be published in the *Federal Register* as required by §§ 51.39 and 51.119.

(c) A draft finding will be distributed as provided in § 51.74(a). Additional copies will be made available in accordance with § 51.123.

(d) When a draft finding of no new and significant information is issued for a proposed action, a final determination to prepare a supplemental environmental impact statement under

§ 51.75(d), or a final finding of no new and significant information for the combined license under § 51.38, shall not be made until the last day of the public comment period has expired.

(e) Based upon public comments, the appropriate director will either prepare a supplement to the early site permit environmental impact statement, or prepare a proposed final finding of no new and significant information. If the director prepares a supplement to the environmental impact statement, the director shall publish a notice of intent in the *Federal Register* as provided in §§ 51.26 and 51.27, unless a notice of intent was published under § 51.26(d). If the director prepares a supplement to the environmental impact statement, the director may conduct scoping.

130. A new § 51.38 is added to read as follows:

§ 51.38 Final finding of no new and significant information.

(a) No later than 180 days after the close of the public comment period, the appropriate NRC staff director shall either publish in the *Federal Register*, in accordance with § 51.23, a notice of intent to prepare a supplement to the early site permit environmental impact statement or transmit the proposed final finding of no new and significant information to the Commission for its consideration. The 180 day period for publication or transmittal may be extended by the Commission.

(b) The Commission, upon review of the proposed final finding, may either:

(1) Direct that the NRC staff prepare a supplement to the early site permit environmental impact statement; or

(2) Issue a final finding of no new and significant information.

(c) If the Commission directs that the staff prepare a supplement to the environmental impact statement, the appropriate director shall publish a notice of intent in the *Federal Register* as provided in §§ 51.26 and 51.27, unless a notice of intent was published under § 51.26(d). If

the director prepares a supplement to the environmental impact statement, the director may conduct scoping.

131. A new § 51.39 is added to read as follows:

§ 51.39 Publication of draft and final finding of no new and significant information; limitation on NRC action.

(a) Whenever the Commission makes a draft or final finding of no new and significant information, the finding will be published in the *Federal Register* as provided in § 51.119.

(b) Except as provided in § 51.13, the appropriate NRC staff director may not issue the combined license under 10 CFR 2.340(g) until after the final finding has been published in the *Federal Register*.

132. In § 51.45, paragraphs (a) and (c) are revised to read as follows:

§ 51.45 Environmental report.

(a) *General.* As required by § 51.50, § 51.53, § 51.54, § 51.55, § 51.60, § 51.61, § 51.62, or § 51.68, as appropriate, each applicant or petitioner for rulemaking shall submit with its application or petition for rulemaking one signed original of a separate document entitled “Applicant’s” or “Petitioner’s Environmental Report,” as appropriate. An applicant or petitioner for rulemaking may submit a supplement to an environmental report at any time.

* * * * *

(c) *Analysis.* The environmental report shall include an analysis that considers and balances the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental effects. Except for environmental reports prepared at the early site permit stage

under § 51.50(b), or environmental reports prepared at the license renewal stage under § 51.53(c), the analysis in the environmental report should also include consideration of the economic, technical, and other benefits and costs of the proposed action and of alternatives. Environmental reports prepared at the license renewal stage under § 51.53(c) need not discuss the economic or technical benefits and costs of either the proposed action or alternatives except insofar as these benefits and costs are either essential for a determination regarding the inclusion of an alternative in the range of alternatives considered or relevant to mitigation. In addition, environmental reports prepared under § 51.53(c) need not discuss issues not related to the environmental effects of the proposed action and its alternatives. The analyses for environmental reports shall, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that cannot be quantified, those considerations or factors shall be discussed in qualitative terms. The environmental report should contain sufficient data to aid the Commission in its development of an independent analysis.

* * * * *

133. Section 51.50 is revised to read as follows:

§ 51.50 Environmental report—construction permit, early site permit, or combined license stage.

(a) *Construction permit stage.* Each applicant for a permit to construct a production or utilization facility covered by § 51.20 shall submit with its application a separate document, entitled “Applicant’s Environmental Report–Construction Permit Stage,” which shall contain the information specified in §§ 51.45, 51.51 and 51.52. Each environmental report shall identify procedures for reporting and keeping records of environmental data, and any conditions and

monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter.

(b) *Early site permit stage.* Each applicant for an early site permit shall submit with its application a separate document, entitled “Applicant’s Environmental Report–Early Site Permit Stage,” which shall contain the information specified in §§ 51.45, 51.51, and 51.52, as modified in this paragraph.

(1) The environmental report must include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed.

(2) The environmental report may address one or more of the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, *provided however*, that the environmental report must address all environmental effects of construction and operation necessary to determine whether there is any obviously superior alternative to the site proposed. The environmental report need not include an assessment of the economic, technical or other benefits (for example, need for power) and costs of the proposed action or an evaluation of alternative energy sources.

(3) For other than light-water-cooled nuclear power reactors, the environmental report must contain the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear power reactor.

(4) Each environmental report must identify the procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter.

(c) *Combined license stage.* Each applicant for a combined license shall submit with its application a separate document, entitled “Applicant’s Environmental Report–Combined

License Stage.” Each environmental report shall contain the information specified in §§ 51.45, 51.51, and 51.52, as modified in this paragraph. For other than light-water-cooled nuclear power reactors, the environmental report shall contain the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear power reactor. Each environmental report shall identify procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter. The combined license environmental report may reference information contained in a final environmental document previously prepared by the NRC staff.

(1) *Application referencing an early site permit.* If the combined license application references an early site permit, then the “Applicant’s Environmental Report–Combined License Stage” need not contain information or analyses submitted to the Commission in “Applicant’s Environmental Report–Early Site Permit Stage,” or resolved in the Commission’s early site permit environmental impact statement, but must contain, in addition to the environmental information and analyses otherwise required:

(i) Information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit;

(ii) Information to resolve any significant environmental issue that was not resolved in the early site permit proceeding;

(iii) Any new and significant information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding; and

(iv) A description of the process used to identify new and significant information regarding the NRC’s conclusions in the early site permit environmental impact statement. The

process must use a reasonable methodology for identifying such new and significant information.

(v) A demonstration that all environmental terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the combined license.

(2) *Application referencing standard design certification.* If the combined license references a standard design certification, then the combined license environmental report may incorporate by reference the environmental assessment previously prepared by the NRC for the referenced design certification. If the design certification environmental assessment is referenced, then the combined license environmental report must contain information to demonstrate that the site characteristics for the combined license site fall within the site parameters in the design certification environmental assessment.

(3) *Application referencing a manufactured reactor.* If the combined license application proposes to use a manufactured reactor, then the combined license environmental report may incorporate by reference the environmental assessment previously prepared by the NRC for the underlying manufacturing license. If the manufacturing license environmental assessment is referenced, then the combined license environmental report must contain information to demonstrate that the site characteristics for the combined license site fall within the site parameters in the manufacturing license environmental assessment. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

134. In § 51.51 paragraph (a) is revised to read as follows:

§ 51.51 Uranium fuel cycle environmental data—Table S-3.

(a) Under § 51.50, every environmental report prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, and submitted on or after September 4, 1979, shall take Table S-3, Table of Uranium Fuel Cycle Environmental Data, as the basis for evaluating the contribution of the environmental effects of uranium mining and milling, the production of uranium hexafluoride, isotopic enrichment, fuel fabrication, reprocessing of irradiated fuel, transportation of radioactive materials and management of low-level wastes and high-level wastes related to uranium fuel cycle activities to the environmental costs of licensing the nuclear power reactor. Table S-3 shall be included in the environmental report and may be supplemented by a discussion of the environmental significance of the data set forth in the table as weighed in the analysis for the proposed facility.

* * * * *

135. In § 51.52, the introductory paragraph is revised to read as follows:

§ 51.52 Environmental effects of transportation of fuel and waste—Table S-4.

Under § 51.50, every environmental report prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, and submitted after February 4, 1975, shall contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. That statement shall indicate that the reactor and this transportation either meet all of the conditions in paragraph (a) of this section or all of the conditions of paragraph (b) of this section.

* * * * *

136. In § 51.53, paragraph (a) and the introductory text of paragraph (c)(3) are revised to read as follows:

§ 51.53 Postconstruction environmental reports.

(a) *General.* Any environmental report prepared under the provisions of this section may incorporate by reference any information contained in a prior environmental report or supplement thereto that relates to the production or utilization facility or site, or any information contained in a final environmental document previously prepared by the NRC staff that relates to the production or utilization facility or site. Documents that may be referenced include, but are not limited to, the final environmental impact statement; supplements to the final environmental impact statement, including supplements prepared at the license renewal stage; NRC staff-prepared final generic environmental impact statements; and environmental assessments and records of decisions prepared in connection with the construction permit, operating license, early site permit, combined license and any license amendment for that facility.

* * * * *

(c) * * *

(3) For those applicants seeking an initial renewed license and holding an operating license, construction permit, or combined license as of June 30, 1995, the environmental report shall include the information required in paragraph (c)(2) of this section subject to the following conditions and considerations:

* * * * *

137. Section 51.54 is revised to read as follows:

§ 51.54 Environmental report-manufacturing license.

(a) Each applicant for a manufacturing license under subpart F of part 52 of this chapter shall submit with its application a separate document entitled, "Applicant's Environmental Report – Manufacturing License." The environmental report must address the costs and

benefits of severe accident mitigation design alternatives (SAMDA), and the bases for not incorporating SAMDAs into the design of the reactor to be manufactured. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license, the benefits and impacts of utilizing the reactor in a nuclear power plant, or an evaluation of alternative energy sources.

(b) Each applicant for an amendment to a manufacturing license shall submit with its application a separate document entitled, "Applicant's Supplemental Environmental Report--Amendment to Manufacturing License." The environmental report must address whether the design change which is the subject of the proposed amendment either renders a SAMDA previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new SAMDAs that may be reasonably incorporated into the design of the manufactured reactor. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

138. Section 51.55 is redesignated as § 51.58, and is revised to read as follows:

§ 51.58 Environmental report-number of copies; distribution.

(a) Each applicant for a license or permit to site, construct, manufacture, or operate a production or utilization facility covered by §§ 51.20(b)(1), (b)(2), (b)(3), or (b)(4), or § 51.75(e), each applicant for renewal of an operating or combined license for a nuclear power plant, each applicant for a license amendment authorizing the decommissioning of a production or utilization facility covered by § 51.20, and each applicant for a license or license amendment to store spent fuel at a nuclear power plant after expiration of the operating license for the nuclear power plant shall submit a copy to the Director of the Office of Nuclear Reactor Regulation, the Director of the Office of New Reactors, the Director of the Office of Nuclear Material Safety and

Safeguards, or the Director of the Office of Federal and State Materials and Environmental Management Programs, as appropriate.

(b) Each applicant for a license to manufacture a nuclear power reactor, or for an amendment to a license to manufacture, seeking approval of the final design of the nuclear power reactor, under subpart F of part 52 of this chapter shall submit to the Commission an environmental report or any supplement to an environmental report in the manner specified in § 50.3 of this chapter. The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent distribution to parties and Boards in the NRC proceeding; Federal, State, and local officials; and any affected Indian tribes, in accordance with written instructions issued by the Director of the Office of Nuclear Reactor Regulation.

139. Section 51.55 is added to read as follows:

§ 51.55 Environmental report—standard design certification.

(a) Each applicant for a standard design certification under subpart B of part 52 of this chapter shall submit with its application a separate document entitled, “Applicant’s Environmental Report—Standard Design Certification.” The environmental report must address the costs and benefits of severe accident mitigation design alternatives (SAMDA), and the bases for not incorporating SAMDA in the design to be certified.

(b) Each applicant for an amendment to a design certification shall submit with its application a separate document entitled, “Applicant’s Supplemental Environmental Report—Amendment to Standard Design Certification.” The environmental report must address whether the design change which is the subject of the proposed amendment either renders a SAMDA previously rejected in an environmental assessment to become cost beneficial, or

results in the identification of new SAMDAs that may be reasonably incorporated into the design certification.

140. Section 51.66 is revised to read as follows:

§ 51.66 Environmental report-number of copies; distribution.

Each applicant for a license or other form of permission, or an amendment to or renewal of a license or other form of permission issued under parts 30, 32, 33, 34, 35, 36, 39, 40, 61, 70 and/or 72 of this chapter, and covered by §§ 51.60(b)(1) through (6); or by § 51.61 or § 51.62 shall submit to the Director of Nuclear Material Safety and Safeguards an environmental report or any supplement to an environmental report in the manner specified in § 51.58(a). The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent distribution to Federal, State, and local officials, and any affected Indian tribes in accordance with written instructions issued by the Director of Nuclear Material Safety and Safeguards.

141. In § 51.71 paragraph (d) and Footnote 3 are revised to read as follows:

§ 51.71 Draft environmental impact statement—contents.

* * * * *

(d) *Analysis.* Unless excepted in this paragraph or § 51.75, the draft environmental impact statement will include a preliminary analysis that considers and weighs the environmental effects of the proposed action; the environmental impacts of alternatives to the proposed action; and alternatives available for reducing or avoiding adverse environmental effects and consideration of the economic, technical, and other benefits and costs of the proposed action and alternatives and indicate what other interests and considerations of Federal policy, including factors not related to environmental quality if applicable, are relevant to

the consideration of environmental effects of the proposed action identified under paragraph (a) of this section. The draft supplemental environmental impact statement prepared at the license renewal stage under § 51.95(c) need not discuss the economic or technical benefits and costs of either the proposed action or alternatives except if benefits and costs are either essential for a determination regarding the inclusion of an alternative in the range of alternatives considered or relevant to mitigation. In addition, the supplemental environmental impact statement prepared at the license renewal stage need not discuss other issues not related to the environmental effects of the proposed action and associated alternatives. The draft supplemental environmental impact statement for license renewal prepared under § 51.95(c) will rely on conclusions as amplified by the supporting information in the GEIS for issues designated as Category 1 in appendix B to subpart A of this part. The draft supplemental environmental impact statement must contain an analysis of those issues identified as Category 2 in appendix B to subpart A of this part that are open for the proposed action. The analysis for all draft environmental impact statements will, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that cannot be quantified, these considerations or factors will be discussed in qualitative terms. Consideration will be given to compliance with environmental quality standards and requirements that have been imposed by Federal, State, regional, and local agencies having responsibility for environmental protection, including applicable zoning and land-use regulations and water pollution limitations or requirements issued or imposed under the Federal Water Pollution Control Act. The environmental impact of the proposed action will be considered in the analysis with respect to matters covered by environmental quality standards and requirements irrespective of whether a certification or license from the

appropriate authority has been obtained.³ While satisfaction of Commission standards and criteria pertaining to radiological effects will be necessary to meet the licensing requirements of the Atomic Energy Act, the analysis will, for the purposes of NEPA, consider the radiological effects of the proposed action and alternatives.

* * * * *

142. Section 51.75 is revised to read as follows:

§ 51.75 Draft environmental impact statement—construction permit, early site permit, or combined license.

(a) *Construction permit stage.* A draft environmental impact statement relating to issuance of a construction permit for a production or utilization facility will be prepared in accordance with the procedures and measures described in §§ 51.70, 51.71, 51.72, and 51.73. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 shall be evaluated on the basis of impact values set forth in Table S-3, Table of Uranium Fuel Cycle Environmental Data, which shall be set out in the draft environmental impact statement. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the

³Compliance with the environmental quality standards and requirements of the Federal Water Pollution Control Act (imposed by EPA or designated permitting states) is not a substitute for, and does not negate the requirement for NRC to weigh all environmental effects of the proposed action, including the degradation, if any, of water quality, and to consider alternatives to the proposed action that are available for reducing adverse effects. Where an environmental assessment of aquatic impact from plant discharges is available from the permitting authority, the NRC will consider the assessment in its determination of the magnitude of environmental impacts for striking an overall cost-benefit balance at the construction permit and operating license and early site permit and combined license stages, and in its determination of whether the adverse environmental impacts of license renewal are so great that preserving the option of license renewal for energy planning decision-makers would be unreasonable at the license renewal stage. When no such assessment of aquatic impacts is available from the permitting authority, NRC will establish on its own, or in conjunction with the permitting authority and other agencies having relevant expertise, the magnitude of potential impacts for striking an overall cost-benefit balance for the facility at the construction permit and operating license and early site permit and combined license stages, and in its determination of whether the adverse environmental impacts of license renewal are so great that preserving the option of license renewal for energy planning decision-makers would be unreasonable at the license renewal stage.

Table shall be required.⁵ The impact statement shall take account of dose commitments and health effects from fuel cycle effluents set forth in Table S-3 and shall in addition take account of economic, socioeconomic, and possible cumulative impacts and other fuel cycle impacts as may reasonably appear significant.

(b) *Early site permit stage.* A draft environmental impact statement relating to issuance of an early site permit for a production or utilization facility will be prepared in accordance with the procedures and measures described in §§ 51.70, 51.71, 51.72, 51.73, and this section. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 shall be evaluated on the basis of impact values set forth in Table S-3, Table of Uranium Fuel Cycle Environmental Data, which shall be set out in the draft environmental impact statement. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the table shall be required.⁵ The impact statement shall take account of dose commitments and health effects from fuel cycle effluents set forth in Table S-3 and shall in addition take account of economic, socioeconomic, and possible cumulative impacts and other fuel cycle impacts as may reasonably appear significant. The draft environmental impact statement must include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed. The draft environmental impact statement must also include an evaluation of the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, but only to the extent addressed in the early site permit environmental report or otherwise necessary to determine whether there is any obviously superior alternative

⁵Values for releases of Rn-222 and Tc-99 are not given in the Table. The amount and significance of Rn-222 releases from the fuel cycle and Tc-99 releases from waste management or reprocessing activities shall be considered in the draft environmental impact statement and may be the subject of litigation in individual licensing proceedings.

to the site proposed. The draft environmental impact statement must not include an assessment of the economic, technical or other benefits (for example, need for power) and costs of the proposed action or an evaluation of alternative energy sources, unless these matters are addressed in the early site permit environmental report.

(c) *Combined license stage.* A draft environmental impact statement relating to issuance of a combined license that does not reference an early site permit will be prepared in accordance with the procedures and measures described in §§ 51.70, 51.71, 51.72, and 51.73. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 shall be evaluated on the basis of impact values set forth in Table S–3, Table of Uranium Fuel Cycle Environmental Data, which shall be set out in the draft environmental impact statement. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the Table shall be required.⁵ The impact statement shall take account of dose commitments and health effects from fuel cycle effluents set forth in Table S–3 and shall in addition take account of economic, socioeconomic, and possible cumulative impacts and other fuel cycle impacts as may reasonably appear significant. The impact statement will include a discussion of the storage of spent fuel for the nuclear power plant within the scope of the generic determination in § 51.23(a) and in accordance with § 51.23(b).

(d) *Combined license application referencing an early site permit with EIS with unresolved environmental issues.*

(1) The NRC staff shall prepare a supplement to the early site permit environmental impact statement for the combined license application if:

(A) The final environmental impact statement prepared in connection with the early site permit does not disclose the economic, technical or other benefits (for example, need for

power) and costs of the proposed action or does not set forth an evaluation of alternative energy sources;

(B) There is a significant environmental issue related to the impacts of construction or operation of the facility that was not previously resolved in the proceeding on the early site permit; or

(C) There is new and significant information identified with respect to issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding.

(2) The supplement must be prepared in accordance with § 51.92.

(e) Combined license application referencing an early site permit with EIS resolving all environmental issues.

(1) The NRC staff shall prepare a finding of no new and significant information for a combined license application referencing an early site permit only if:

(A) The final environmental impact statement prepared in connection with the early site permit discloses the economic, technical or other benefits (for example, need for power) and costs of the proposed action, contains an evaluation of alternative energy sources and resolves all environmental issues related to the impacts of construction and operation of the facility; and

(B) There is no new and significant information identified with respect to issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding.

(2) The finding of no new and significant information must be prepared in accordance with § 51.36.

(f) Combined license application referencing a standard design certification. If the combined license application references a standard design certification and the site characteristics of the combined license's site fall within the site parameters specified in the

design certification environmental assessment, then the draft combined license environmental impact statement shall incorporate by reference the design certification environmental assessment, and summarize the findings and conclusions of the environmental assessment with respect to severe accident mitigation design alternatives.

(g) *Combined license application referencing a manufactured reactor.* If the combined license application proposes to use a manufactured reactor and the site characteristics of the combined license's site fall within the site parameters specified in the manufacturing license environmental assessment, then the draft combined license environmental impact statement shall incorporate by reference the manufacturing license environmental assessment, and summarize the findings and conclusions of the environmental assessment with respect to SAMDAs. The combined license environmental impact statement report will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

§ 51.76 [Removed and Reserved]

143. Section 51.76 is removed and reserved.

144. Section 51.92 is revised to read as follows:

§ 51.92 Supplement to the final environmental impact statement.

(a) If the proposed action has not been taken, the NRC staff will prepare a supplement to a final environmental impact statement for which a notice of availability has been published in the *Federal Register* as provided in §51.118, if:

(1) There are substantial changes in the proposed action that are relevant to environmental concerns; or

(2) There are new and significant circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts.

(b) In a proceeding for a combined license application under 10 CFR part 52 referencing an early site permit under part 52, the NRC staff shall prepare a supplement to the final environmental impact statement for the referenced early site permit when required by § 51.75(d).

(c) The NRC staff may prepare a supplement to a final environmental impact statement when, in its opinion, preparation of a supplement will further the purposes of NEPA.

(d) The supplement to a final environmental impact statement will be prepared in the same manner as the final environmental impact statement except that a scoping process need not be used.

(e) The supplement to an early site permit final environmental impact statement which is prepared for combined license application in accordance with § 51.75(d) and paragraph (b) of this section must:

(1) Identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application;

(2) Incorporate by reference the final environmental impact statement prepared for the early site permit;

(3) Contain no separate discussion of alternative sites;

(4) Include an analysis of the economic, technical, and other benefits and costs of the proposed action, to the extent that the final environmental impact statement prepared for the early site permit did not include an assessment of these benefits and costs;

(5) Include an analysis of other energy alternatives, to the extent that the final environmental impact statement prepared for the early site permit did not include an assessment of energy alternatives;

(6) Include an analysis of any environmental issue related to the impacts of construction or operation of the facility that was not previously resolved in the proceeding on the early site permit; and

(7) Include an analysis of the issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding for which new and significant information has been identified, including, but not limited to, new and significant information demonstrating that the design of the facility falls outside the site characteristics and design parameters specified in the early site permit.

(f)(1) A supplement to a final environmental impact statement will be accompanied by or will include a request for comments as provided in § 51.73 and a notice of availability will be published in the *Federal Register* as provided in § 51.117 if the conditions described in paragraph (a) of this section apply.

(2) If comments are not requested, a notice of availability of a supplement to a final environmental impact statement will be published in the *Federal Register* as provided in § 51.118.

145. In § 51.95, paragraph (a), the introductory text of paragraph (c), and paragraph (d) are revised to read as follows:

§ 51.95 Postconstruction environmental impact statements.

(a) *General.* Any supplement to a final environmental impact statement or any environmental assessment prepared under the provisions of this section may incorporate by reference any information contained in a final environmental document previously prepared by

the NRC staff that relates to the same production or utilization facility. Documents that may be referenced include, but are not limited to, the final environmental impact statement; supplements to the final environmental impact statement, including supplements prepared at the operating license stage; NRC staff-prepared final generic environmental impact statements; environmental assessments and records of decisions prepared in connection with the construction permit, the operating license, the early site permit, or the combined license and any license amendment for that facility. A supplement to a final environmental impact statement will include a request for comments as provided in § 51.73.

* * * * *

(c) *Operating license renewal stage.* In connection with the renewal of an operating license for a nuclear power plant under parts 52 or 54 of this chapter, the Commission shall prepare an EIS, which is a supplement to the Commission's NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants" (May 1996) which is available in the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland.

* * * * *

(d) *Postoperating license stage.* In connection with the amendment of an operating or combined license authorizing decommissioning activities at a production or utilization facility covered by § 51.20 or § 51.75(e), either for unrestricted use or based on continuing use restrictions applicable to the site, or with the issuance, amendment or renewal of a license to store spent fuel at a nuclear power reactor after expiration of the operating or combined license for the nuclear power reactor, the NRC staff will prepare a supplemental environmental impact statement for the post operating or post combined license stage or an environmental assessment, as appropriate, which will update the prior environmental documentation prepared by the NRC for compliance with NEPA under the provisions of this part. The supplement or assessment may incorporate by reference any information contained in the final environmental

impact statement—for the operating or combined license stage, as appropriate, or in the records of decision prepared in connection with the early site permit, construction permit, operating license, or combined license for that facility. The supplement will include a request for comments as provided in § 51.73. Unless otherwise required by the Commission in accordance with the generic determination in § 51.23(a) and the provisions of § 51.23(b), a supplemental environmental impact statement for the postoperating or post combined license stage or an environmental assessment, as appropriate, will address the environmental impacts of spent fuel storage only for the term of the license, license amendment or license renewal applied for.

146. Section 51.105 is revised to read as follows:

§ 51.105 Public hearings in proceedings for issuance of construction permits or early site permits.

(a) In addition to complying with applicable requirements of § 51.104, in a proceeding for the issuance of a construction permit or early site permit for a nuclear power reactor, testing facility, fuel reprocessing plant or isotopic enrichment plant, the presiding officer will:

(1) Determine whether the requirements of Section 102(2) (A), (C), and (E) of NEPA and the regulations in this subpart have been met;

(2) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken;

(3) Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit or early site permit should be issued, denied, or appropriately conditioned to protect environmental values;

(4) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate; and

(5) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the construction permit or early site permit should be issued as proposed by the NRC's Director of Nuclear Reactor Regulation.

(b) The presiding officer in an early site permit hearing shall not admit contentions proffered by any party concerning the benefits assessment (*e.g.*, need for power) or alternative energy sources if those issues were not addressed by the applicant in the early site permit application.

147. Section 51.105a is added to read as follows:

§ 51.105a Public hearings in proceedings for issuance of manufacturing licenses.

(a) In addition to complying with applicable requirements of § 51.31(c), in a proceeding for the issuance of a manufacturing license, the presiding officer will:

(1) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate to identify all reasonable SAMDAs for the design of the reactor to be manufactured and evaluate the environmental, technical, economic, and other benefits and costs of each SAMDA; and

(2) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the manufacturing license should be issued as proposed by the NRC's Director of Nuclear Reactor Regulation.

148. Section 51.107 is added to read as follows:

§ 51.107 Public hearings in proceedings for issuance of combined licenses.

(a) In addition to complying with the applicable requirements of § 51.104, in a proceeding for the issuance of a combined license for a nuclear power reactor under part 52 of this chapter (except in those cases where a finding of no new and significant information is prepared in accordance with § 51.75(e)), the presiding officer will:

(1) Determine whether the requirements of Section 102(2) (A), (C), and (E) of NEPA and the regulations in this subpart have been met;

(2) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken;

(3) Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the combined license should be issued, denied, or appropriately conditioned to protect environmental values;

(4) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate; and

(5) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the combined license should be issued as proposed by the appropriate NRC staff director.

(b) In addition to complying with the applicable requirements of § 51.104, in a proceeding for the issuance of a combined license for a nuclear power reactor under part 52 of this chapter where a finding of no new and significant information is prepared in accordance with § 51.75(e), the presiding officer will determine whether the NEPA review conducted by the NRC staff has been adequate.

(c) If a combined license application references an early site permit, and a supplement to the early site permit environmental impact statement is prepared in accordance with § 51.75(d) and § 51.92(e), then the presiding officer in the combined license hearing shall not

admit any contention proffered by any party on environmental issues which have been accorded finality under § 52.39 of this chapter, unless the contention:

(1) Demonstrates that the nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(2) Raises any significant environmental issue that was not resolved in the early site permit proceeding; or

(3) Raises any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which new and significant information has been identified.

(d) If a combined license application references an early site permit, and a finding of no new and significant information is prepared in accordance with § 51.75(e) and § 51.36, then the presiding officer in the combined license hearing shall not admit any contention proffered by any party on environmental issues which have been accorded finality under § 52.39 of this chapter, and shall not make any findings with respect to the adequacy of the environmental assessment or the finding of no new and significant information.

(e) If the combined license application references a standard design certification, or proposes to use a manufactured reactor, then the presiding officer in a combined license hearing shall not admit contentions proffered by any party concerning severe accident mitigation design alternatives unless the contention demonstrates that the site characteristics fall outside of the site parameters in the standard design certification or underlying manufacturing license for the manufactured reactor.

149. Section 51.108 is added under the undesignated center heading "Production and Utilization Facilities," to read as follows:

§ 51.108 Public hearings on Commission findings that inspections, tests, analyses, and acceptance criteria of combined licenses are met.

In any public hearing requested under 10 CFR 52.103(b), the Commission will not admit any contentions on environmental issues, the adequacy of the environmental impact statement for the combined license issued under subpart C of part 52, or the adequacy of any other environmental impact statement or environmental assessment referenced in the combined license application. The Commission will not make any environmental findings in connection with the finding under 10 CFR 52.103(g).

150. In § 51.119, the section heading and paragraphs (a) and (b) are revised to read as follows:

§ 51.119 Publication of finding of no significant impact, or no new and significant information; distribution.

(a) As required by §§ 51.35, 51.37, or 51.38, as applicable, the appropriate NRC staff director will publish a finding of no significant impact or no new and significant information in the *Federal Register*. The finding will be identified as a draft or final finding, and will contain the information specified in §§ 51.32, 51.33, 51.36, or 51.37 as appropriate. A draft finding will include a request for comments which specifies where comments should be submitted and when the comment period expires.

(b) The finding will state that copies of the finding, the environmental assessment or finding of no new and significant information, as applicable, setting forth the basis for the finding and any related environmental documents are available for public inspection and where inspection may be made.

* * * * *

151. Section 51.120 is revised to read as follows:

§ 51.120 Availability of environmental documents for public inspection.

Copies of environmental reports, draft and final environmental impact statements, environmental assessments, findings of no significant impact, and findings of no new and significant information, together with any related comments and environmental documents, will be made available at the NRC Web site, *http://www.nrc.gov*, and/or at the NRC Public Document Room.

152. Part 52 is revised to read as follows:

PART 52 – LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER

PLANTS

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APPENDIX O TO PART 52 [RESERVED]

APPENDIX P TO PART 52 [RESERVED]

APPENDIX Q TO PART 52—PRE-APPLICATION EARLY REVIEW OF SITE SUITABILITY
ISSUES

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954,
955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2133, 2201, 2232,
2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended
(42 U.S.C. 5841, 5842, 5846).

General Provisions

§ 52.0 Scope; applicability of 10 CFR Chapter 1 provisions.

(a) This part governs the issuance of early site permits, standard design certifications, combined licenses, standard design approvals, and manufacturing licenses for nuclear power facilities licensed under Section 103 of the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). This part also gives notice to all persons who knowingly provide to any holder of or applicant for an approval, certification, permit, or license, or to a contractor, subcontractor, or consultant of any of them, components, equipment, materials, or other goods or services that relate to the activities of a holder of or applicant for an approval, certification, permit, or license, subject to this part, that they may be individually subject to NRC enforcement action for violation of the provisions in 10 CFR 52.4.

(b) Unless otherwise specifically provided for in this part, the regulations in 10 CFR Chapter 1 apply to a holder of or applicant for an approval, certification, permit, or license. A holder of or applicant for an approval, certification, permit, or license issued under this part shall comply with all requirements in 10 CFR Chapter 1 that are applicable. A license, approval, certification, or permit issued under this part is subject to all requirements in 10 CFR Chapter 1 which, by their terms, are applicable to early site permits, design certifications, combined licenses, design approvals, or manufacturing licenses.

§ 52.1 Definitions.

(a) As used in this part - -

Combined license means a combined construction permit and operating license with conditions for a nuclear power facility issued under subpart C of this part.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits - -

(i) Release of the property for unrestricted use and termination of the license; or

(ii) Release of the property under restricted conditions and termination of the license.

Design characteristics are the actual features of a reactor or reactors. Design characteristics are specified in a standard design approval, a standard design certification, a combined license application, or a manufacturing license.

Design parameters are the postulated features of a reactor or reactors that could be built at a proposed site. Design parameters are specified in an early site permit.

Early site permit means a Commission approval, issued under subpart A of this part, for a site or sites for one or more nuclear power facilities. An early site permit is a partial construction permit.

License means a license, including an early site permit, combined license or manufacturing license under this part or a renewed license issued by the Commission under this part or part 54 of this chapter.

Licensee means a person who is authorized to conduct activities under a license issued by the Commission.

Major feature of the emergency plans means an aspect of those plans necessary to:

- (i) Address in whole or part one or more of the 16 standards in 10 CFR 50.47(b); or
- (ii) Describe the emergency planning zones as required in 10 CFR 50.33(g).

Manufacturing license means a license, issued under subpart F of this part, authorizing the manufacture of nuclear power reactors but not their construction, installation, or operation at the sites on which the reactors are to be operated.

Modular design means a nuclear power station that consists of two or more essentially identical nuclear reactors (modules) and each module is a separate nuclear reactor capable of being operated independent of the state of completion or operating condition of any other module co-located on the same site, even though the nuclear power station may have some shared or common systems.

Prototype plant means a nuclear power plant that is used to test new safety features, such as the testing required under 10 CFR 50.43(e). The prototype plant is similar to a first-of-a-kind or standard plant design in all features and size, but may include additional safety features to protect the public and the plant staff from the possible consequences of accidents during the testing period.

Site characteristics are the actual physical, environmental and demographic features of a site. Site characteristics are specified in an early site permit or in a final safety analysis report for a combined license.

Site parameters are the postulated physical, environmental and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or manufacturing license.

Standard design means a design which is sufficiently detailed and complete to support certification or approval in accordance with subpart B or E of this part, and which is usable for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

Standard design approval or design approval means an NRC staff approval, issued under subpart E of this part, of a final standard design for a nuclear power reactor of the type described in 10 CFR 50.22. The approval may be for either the final design for the entire reactor facility or the final design of major portions thereof.

Standard design certification or design certification means a Commission approval, issued under subpart B of this part, of a final standard design for a nuclear power facility. This design may be referred to as a *certified standard design*.

(b) All other terms in this part have the meaning set out in 10 CFR 50.2, or Section 11 of the Atomic Energy Act, as applicable.

§52.2 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 52.3 Written communications.

(a) *General requirements.* All correspondence, reports, applications, and other written communications from an applicant, licensee, or holder of a standard design approval to the Nuclear Regulatory Commission concerning the regulations in this part, individual license conditions, or the terms and conditions of an early site permit or standard design approval, must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail at EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(b) *Distribution requirements.* Copies of all correspondence, reports, and other written communications concerning the regulations in this part or individual license conditions, or the terms and conditions of an early site permit or standard design approval, must be submitted to the persons listed in paragraph (b)(1) of this section (addresses for the NRC Regional Offices are listed in appendix D to part 20 of this chapter).

(1) *Applications for amendment of permits and licenses; reports; and other communications.* All written communications (including responses to: generic letters, bulletins, information notices, regulatory information summaries, inspection reports, and miscellaneous requests for additional information) that are required of holders of early site permits, standard design approvals, combined licenses, or manufacturing licenses issued under this part must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (b)(7) of this section: to the NRC's Document Control Desk (if on paper, the signed original), with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under subpart F of this part.

(2) *Applications and amendments to applications.* Applications for early site permits, standard design approvals, combined licenses, manufacturing licenses and amendments to any of these types of applications must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under subpart F of this part, except as otherwise specified in paragraphs (b)(3) through (b)(7) of this section. If the application or amendment is on paper, the submission to the Document Control Desk must be the signed original.

(3) *Acceptance review application.* Written communications required for an application for determination of suitability for docketing must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(4) *Security plan and related submissions.* Written communications, as defined in paragraphs (b)(4)(i) through (iv) of this section, must be submitted to the NRC's Document

Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(i) Physical security plan under § 52.79 of this chapter;

(ii) Safeguards contingency plan under § 52.79 of this chapter;

(iii) Change to security plan, guard training and qualification plan, or safeguards contingency plan made without prior Commission approval under § 50.54(p) of this chapter;

(iv) Application for amendment of physical security plan, guard training and qualification plan, or safeguards contingency plan under § 50.90 of this chapter.

(5) *Emergency plan and related submissions.* Written communications as defined in paragraphs (b)(5)(i) through (iii) of this section must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(i) Emergency plan under § 52.17(b) or § 52.79(a);

(ii) Change to an emergency plan under § 50.54(q) of this chapter;

(iii) Emergency implementing procedures under appendix E, Section V of part 50 of this chapter.

(6) *Updated FSAR.* An updated final safety analysis report (FSAR) or replacement pages under § 50.71(e) of this chapter, or the regulations in this part must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under subpart F of this part. Paper copy submissions may be made using replacement pages; however, if a licensee chooses to use electronic submission, all subsequent updates or submissions must be performed electronically

on a total replacement basis. If the communication is on paper, the submission to the Document Control Desk must be the signed original. If the communications are submitted electronically, see Guidance for Electronic Submissions to the Commission.

(7) *Quality assurance related submissions.*

(i) A change to the safety analysis report quality assurance program description under § 50.54(a)(3) or § 50.55(f)(4) of this chapter, or a change to a licensee's NRC-accepted quality assurance topical report under § 50.54(a)(3) or § 50.55(f)(4) of this chapter, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(ii) A change to an NRC-accepted quality assurance topical report from nonlicensees (*i.e.*, architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent.

(8) *Certification of permanent cessation of operations.* The licensee's certification of permanent cessation of operations under § 52.110(a)(1), must state the date on which operations have ceased or will cease, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(9) *Certification of permanent fuel removal.* The licensee's certification of permanent fuel removal under § 52.110(a)(1), must state the date on which the fuel was removed from the reactor vessel and the disposition of the fuel, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(c) *Form of communications.* All paper copies submitted to meet the requirements set forth in paragraph (b) of this section must be typewritten, printed or otherwise reproduced in

permanent form on unglazed paper. Exceptions to these requirements imposed on paper submissions may be granted for the submission of micrographic, photographic, or similar forms.

(d) *Regulation governing submission.* Applicants, licensees, and holders of standard design approvals submitting correspondence, reports, and other written communications under the regulations of this part are requested but not required to cite whenever practical, in the upper right corner of the first page of the submission, the specific regulation or other basis requiring submission.

§ 52.4 Deliberate misconduct.

(a) *Applicability.* This section applies to any:

- (1) Licensee;
- (2) Holder of a standard design approval;
- (3) Applicant for a standard design certification;
- (4) Applicant for a license or permit;
- (5) Applicant for a standard design approval;
- (6) Employee of a licensee;
- (7) Employee of an applicant for a license, a standard design certification, or a standard design approval;
- (8) Any contractor (including a supplier or consultant), subcontractor, or employee of a contractor or subcontractor of any licensee; or
- (9) Any contractor (including a supplier or consultant), subcontractor, or employee of a contractor or subcontractor of any applicant for a license, a standard design certification, or a standard design approval.

(b) *Definitions.* For purposes of this section:

Deliberate misconduct means an intentional act or omission that a person or entity knows:

(i) Would cause a licensee or an applicant for a license, standard design certification, or standard design approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license, standard design certification, or standard design approval; or

(ii) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, or contractor, or subcontractor.

(c) *Prohibition against deliberate misconduct.* Any person or entity subject to this section, who knowingly provides to any licensee, any applicant for a license, standard design certification or standard design approval, or a contractor, or subcontractor of a person or entity subject to this section, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities under this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, holder of a standard design approval, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission, any standard design approval, or standard design certification; or

(2) Deliberately submit to the NRC; a licensee, an applicant for a license, standard design certification or standard design approval; or a licensee's, standard design approval holder's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(d) A person or entity who violates paragraph (c)(1) or (c)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

§ 52.5 Employee protection.

(a) Discrimination by a Commission licensee, holder of a standard design approval, an applicant for a license, standard design certification, or standard design approval, a contractor or subcontractor of a Commission licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in Section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in the introductory text of paragraph (a) of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in the introductory text of paragraph (a) of this section or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in the introductory text of paragraph (a) of this section; and

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, a holder of a standard design approval, an applicant for a Commission license, standard design certification, or a standard design approval, or a contractor or subcontractor of a Commission licensee, holder of a standard design approval, or any applicant may be grounds for—

(1) Denial, revocation, or suspension of the license or standard design approval;

(2) Withdrawal or revocation of a proposed or final standard design certification;

(3) Imposition of a civil penalty on the licensee, holder of a standard design approval, or applicant (including an applicant for a standard design certification under this part following Commission adoption of final design certification rule).

(4) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's

engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee, each holder of a standard design approval, and each applicant for a license, standard design certification, or standard design approval, shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(e). This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than thirty (30) days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, standard design certification, or standard design approval under 10 CFR part 52, and for 30 days following license termination or the expiration or termination of the standard design certification or standard design approval under 10 CFR part 52.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-6157, via e-mail to forms@nrc.gov, or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the NRC's home page.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor under Section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

(g) Part 19 of this chapter sets forth requirements and regulatory provisions applicable to licensees, holders of a standard design approval, applicants for a license, standard design certification, or standard design approval, and contractors or subcontractors of a Commission licensee, or holder of a standard design approval, and are in addition to the requirements in this section.

§ 52.6 Completeness and accuracy of information.

(a) Information provided to the Commission by a licensee (including an early site permit holder, a combined license holder, and a manufacturing license holder), a holder of a standard design approval under this part, and an applicant for a license or an applicant for a standard design certification or a standard design approval under this part, and information required by statute or by the Commission's regulations, orders, license conditions, or terms and conditions of a standard design approval to be maintained by the licensee, the holder of a standard design approval under this part, the applicant for a standard design certification under this part following Commission adoption of a final design certification rule, and an applicant for a license, a standard design certification, or a standard design approval under this part shall be complete and accurate in all material respects.

(b) Each applicant or licensee, each holder of a standard design approval under this part, and each applicant for a standard design certification under this part following Commission adoption of a final design certification regulation, shall notify the Commission of information identified by the applicant or the licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant, licensee, or holder violates this paragraph only if the applicant, licensee, or holder fails to notify the Commission of information that the applicant, licensee, or holder has been identified as having a significant implication for public health and safety or common defense and security.

Notification shall be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

§ 52.7 Specific exemptions.

The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part. The Commission's consideration will be governed by § 50.12 of this chapter, unless other criteria are provided for in this part, in which case the Commission's consideration will be governed by the criteria in this part. Only if those criteria are not met will the Commission's consideration be governed by § 50.12 of this chapter. The Commission's consideration of requests for exemptions from requirements of the regulations of other parts in this chapter, which are applicable by virtue of this part, shall be governed by the exemption requirements of those parts.

§ 52.8 Combining licenses; elimination of repetition.

(a) An applicant for a license under this part may combine in its application several applications for different kinds of licenses under the regulations of this chapter.

(b) An applicant may incorporate by reference in its application information contained in previous applications, statements or reports filed with the Commission, *provided, however*, that such references are clear and specific.

(c) The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 52.9 Jurisdictional limits.

No permit license, standard design approval, or standard design certification under this part shall be deemed to have been issued for activities which are not under or within the jurisdiction of the United States.

§ 52.10 Attacks and destructive acts.

Neither an applicant for a license to manufacture, construct, and operate a utilization facility under this part, nor for an amendment to this license, or an applicant for an early site permit, a standard design certification, or standard design approval under this part, or for an amendment to the early site permit, standard design certification, or standard design approval, is required to provide for design features or other measures for the specific purpose of protection against the effects of-

- (a) Attacks and destructive acts, including sabotage, directed against the facility by an enemy of the United States, whether a foreign government or other person; or
- (b) Use or deployment of weapons incident to U.S. defense activities.

§ 52.11 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under Control Number 3150-0151.

(b) The approved information collection requirements contained in this part appear in §§ 52.7, 52.15, 52.16, 52.17, 52.29, 52.35, 52.39, 52.45, 52.46, 52.47, 52.57, 52.63, 52.75, 52.77, 52.79, 52.80, 52.93, 52.99, 52.110, 52.135, 52.136, 52.137, 52.155, 52.156, 52.157, 52.158, 52.171, 52.177, and appendices A, B, C, D, N, and Q of part 52.

Subpart A – Early Site Permits

§ 52.12 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of an early site permit for approval of a site for one or more nuclear power facilities separate from the filing of an application for a construction permit or combined license for the facility.

§ 52.13 Relationship to other subparts.

This subpart applies when any person who may apply for a construction permit under 10 CFR part 50, or for a combined license under this part seeks an early site permit from the Commission separately from an application for a construction permit or a combined license.

§ 52.15 Filing of applications.

(a) Any person who may apply for a construction permit under 10 CFR part 50, or for a combined license under this part, may file an application for an early site permit with the Director, Office of New Reactors, or the Director, Office of Nuclear Reactor Regulation, as appropriate. An application for an early site permit may be filed notwithstanding the fact that an

application for a construction permit or a combined license has not been filed in connection with the site for which a permit is sought.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.

(c) The fees associated with the filing and review of an application for the initial issuance or renewal of an early site permit are set forth in 10 CFR part 170.

§ 52.16 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (d) and (j) of this chapter.

§ 52.17 Contents of applications; technical information.

(a) The application must contain:

(1) A site safety analysis report. The site safety analysis report shall include the following:

(i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;

(ii) The anticipated maximum levels of radiological and thermal effluents each facility will produce;

(iii) The type of cooling systems, intakes, and outflows that may be associated with each facility;

(iv) The boundaries of the site;

(v) The proposed general location of each facility on the site;

(vi) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that

have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated;

(vii) The location and description of any nearby industrial, military, or transportation facilities and routes;

(viii) The existing and projected future population profile of the area surrounding the site;

(ix) A description and safety assessment of the site on which a facility is to be located.

The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(ix)(A) and (a)(1)(ix)(B) of this section. In performing this assessment, an applicant shall assume a fission product release¹ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

¹The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

(A) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem² total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(x) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed;

(xi) For applications submitted after **[INSERT DATE OF FINAL RULE]**, a description of the quality assurance program applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Appendix B to 10 CFR part 50 sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant site shall include a discussion of how the applicable requirements of appendix B to part 50 of this chapter will be satisfied; and

(xii) An evaluation of the site against applicable sections of the NRC's application and review guidance in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in analytical techniques and procedural measures proposed for a site and those corresponding techniques and measures given in the acceptance criteria in the application and review

²A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accidents.

guidance. Where such a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding acceptance criteria. The NRC's application and review guidance is not a substitute for the regulations, and compliance is not a requirement.

(2) A complete environmental report as required by 10 CFR 51.50(b).

(b)(1) The site safety analysis report must identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. If physical characteristics are identified that could pose a significant impediment to the development of emergency plans, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment.

(2) The site safety analysis report may also:

(i) Propose major features of the emergency plans, in accordance with the pertinent standards of 10 CFR 50.47, and the requirements of appendix E to 10 CFR part 50, such as the exact size and configuration of the emergency planning zones, for review and approval by NRC, in consultation with the Department of Homeland Security (DHS) in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans for review and approval by the NRC, in consultation with DHS, in accordance with the applicable standards of 10 CFR 50.47, and the requirements of appendix E to 10 CFR part 50. To the extent approval of emergency plans is sought, the application must contain the information required by §§ 50.33(g) and (j) of this chapter.

(3) Emergency plans submitted under paragraph (b)(2)(ii) of this section must include the proposed inspections, tests, and analyses that the holder of a combined license referencing

the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC's regulations. Major features of an emergency plan submitted under paragraph (b)(2)(i) of this section may include proposed inspections, tests, analyses, and acceptance criteria.

(4) Under paragraphs (b)(1) and (b)(2)(i) of this section, the site safety analysis report must include a description of contacts and arrangements made with Federal, State, and local governmental agencies with emergency planning responsibilities. The site safety analysis report must contain any certifications that have been obtained. If these certifications cannot be obtained, the site safety analysis report must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site. Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant shall make good faith efforts to obtain from the same governmental agencies certifications that:

- (i) The proposed emergency plans are practicable;
- (ii) These agencies are committed to participating in any further development of the plans, including any required field demonstrations, and
- (iii) That these agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(c) If the applicant requests authorization to perform activities at the site, which are identified in 10 CFR 50.10(e)(1), after issuance of the early site permit and without a separate authorization under 10 CFR 50.10(e)(1), the applicant must identify and the activities that are requested, and propose a plan for redress of the site in the event that the activities are performed and the early site permit expires before it is referenced in an application for a

construction permit or a combined license. The application must demonstrate that there is reasonable assurance that redress carried out under the plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

§ 52.18 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR part 50 and its appendices and 10 CFR part 100. In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR part 51. The Commission shall determine, after consultation with DHS, whether the information required of the applicant by § 52.17(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 52.17(b)(2)(i) are acceptable in accordance with the applicable standards of 10 CFR 50.47 and the requirements of appendix E to 10 CFR part 50, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

§ 52.21 Administrative review of applications: hearings.

An early site permit is subject to all procedural requirements in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of hearing in §§ 2.104(a) and (d) of this chapter, provided that the designated sections may not be construed to require that the environmental report, or draft or final environmental impact statement include an assessment of the benefits of

construction and operation of the reactor or reactors, or an analysis of alternative energy sources. The presiding officer in an early site permit hearing shall not admit contentions proffered by any party concerning an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources if those issues were not addressed by the applicant in the early site permit application. All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR part 2, as applicable.

§ 52.23 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application for an early site permit to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.24 Issuance of early site permit.

(a) After conducting a hearing under § 52.21 and receiving the report to be submitted by the ACRS under § 52.23, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that:

- (1) An application for an early site permit meets the applicable standards and requirements of the Act and the Commission's regulations;
- (2) Notifications, if any, to other agencies or bodies have been duly made;
- (3) There is reasonable assurance that the site is in conformity with the provisions of the Act, and the Commission's regulations;
- (4) The applicant is technically qualified to engage in any activities authorized;
- (5) The proposed inspections, tests, analyses and acceptance criteria, including any on emergency planning, are necessary and sufficient, within the scope of the early site permit, to

provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;

(7) Any significant adverse environmental impact resulting from activities requested under § 52.17(c) can be redressed; and

(8) The findings required by subpart A of 10 CFR part 51 have been made.

(b) The early site permit must specify the site characteristics, design parameters, and terms and conditions of the early site permit the Commission deems appropriate. Before issuance of either a construction permit or combined license referencing an early site permit, the Commission shall find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions of the early site permit that could not be met by the time of issuance of the construction permit or combined license, must be set forth as terms or conditions of the construction permit or combined license.

(c) The early site permit shall specify the activities under § 52.17(c) that the permit holder is authorized to perform.

§ 52.25 Extent of activities permitted.

If the activities authorized by § 52.24(c) are performed and the site is not referenced in an application for a construction permit or a combined license issued under subpart C of this part while the permit remains valid, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit shall redress the site in accordance with the terms of the site redress plan required by § 52.17(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 52.27 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 10, nor more than 20 years from the date of issuance.

(b) An early site permit continues to be valid beyond the date of expiration in any proceeding on a construction permit application or a combined license application that references the early site permit and is docketed before the date of expiration of the early site permit, or, if a timely application for renewal of the permit has been docketed, before the Commission has determined whether to renew the permit.

(c) An applicant for a construction permit or combined license may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

(d) Upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license.

§ 52.28 Transfer of early site permit.

An application to transfer an early site permit will be processed under 10 CFR 50.80.

§ 52.29 Application for renewal.

(a) Not less than 12, nor more than 36 months before the expiration date stated in the early site permit, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR 2.309. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.309.

(c) An early site permit, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in certain proceedings in accordance with the provisions of § 52.27(b).

(d) The Commission shall refer a copy of the application for renewal to the ACRS. The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.31.

§ 52.31 Criteria for renewal.

(a) The Commission shall grant the renewal if it determines that:

(1) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and

(2) Any new requirements the Commission may wish to impose are:

(i) Necessary for adequate protection to public health and safety or common defense and security;

(ii) Necessary for compliance with the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; or

(iii) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal for failure to comply with the provisions of § 52.31(a) does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.

§ 52.33 Duration of renewal.

Each renewal of an early site permit may be for not less than 10, nor more than 20 years, plus any remaining years on the early site permit then in effect before renewal.

§ 52.35 Use of site for other purposes.

A site for which an early site permit has been issued under this subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder shall inform the Director of New Reactors or the Director of Nuclear Reactor Regulation, as appropriate, (Director) of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, in accordance with the provisions of § 52.39. If the permit holder informs the Director that the holder no longer intends to use the site for a nuclear power plant, the Director may terminate the permit.

§ 52.39 Finality of early site permit determinations.

(a) *Commission finality.* (1) Notwithstanding any provision in 10 CFR 50.109, while an early site permit is in effect under §§ 52.27 or 52.33, the Commission may not change or

impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission:

(i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;

(ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;

(iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or

(iv) Issues a variance requested under paragraph (d) of this section.

(2) In making the findings required for issuance of a construction permit or combined license, or the findings required by § 52.103, or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, if the application for the construction permit or combined license references an early site permit, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(i) If the early site permit approved an emergency plan (or major features thereof) that is in use by a licensee of a nuclear power plant, the Commission shall treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee's emergency plans in compliance with § 50.54(q) of this chapter occurring after issuance of the early site permit.

(ii) If the early site permit approved an emergency plan (or major features thereof) that is not in use by a licensee of a nuclear power plant, the Commission shall treat as resolved

changes that are equivalent to those that could be made under § 50.54(q) of this chapter without prior NRC approval had the emergency plan been in use by a licensee.

(b) *Updating of early site permit-emergency preparedness.* An applicant for a construction permit, operating license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update the emergency preparedness information that was provided under § 52.17(b), and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

(c) *Hearings and petitions.* (1) In any proceeding for the issuance of a construction permit, operating license, or combined license referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness; or

(v) Any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified.

(2) Any person may file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit should be modified, or that the

permit should be suspended or revoked. The petition will be considered in accordance with § 2.206 of this chapter. Before construction commences, the Commission shall consider the petition and determine whether any immediate action is required. If the petition is granted, an appropriate order will be issued. Construction under the construction permit or combined license will not be affected by the granting of the petition unless the order is made immediately effective. Any change required by the Commission in response to the petition must meet the requirements of paragraph (a)(1) of this section.

(d) *Variances.* An applicant for a construction permit, operating license, or combined license referencing an early site permit may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the site safety analysis report. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. Once a construction permit or combined license referencing an early site permit is issued, variances from the early site permit will not be granted for that construction permit or combined license.

(e) The holder of an early site permit may not make changes to the early site permit, including the site safety analysis report, without prior Commission approval. The request for a change to the early site permit must be in the form of an application for a license amendment, and must meet the requirements of 10 CFR 50.90 and 50.92.

(f) *Information requests.* Except for information requests seeking to verify compliance with the current licensing basis of the early site permit, information requests to the holder of an early site permit must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in

accordance with 10 CFR 50.54(f), and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

Subpart B – Standard Design Certifications

§ 52.41 Scope of subpart.

(a) This subpart sets forth the requirements and procedures applicable to Commission issuance of rules granting standard design certifications for nuclear power facilities separate from the filing of an application for a construction permit or combined license for such a facility.

(b)(1) Any person may seek a standard design certification for an essentially complete nuclear power plant design which is an evolutionary change from light water reactor designs of plants which have been licensed and in commercial operation before April 18, 1989.

(2) Any person may also seek a standard design certification for a nuclear power plant design which differs significantly from the light water reactor designs described in paragraph (b)(1) of this section or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions.

§ 52.43 Relationship to other subparts.

(a) This subpart applies to a person that requests a standard design certification from the NRC separately from an application for a combined license filed under subpart C of this part for a nuclear power facility. An applicant for a combined license may reference a standard design certification.

(b) Subpart E of this part governs the NRC staff review and approval of a final standard design. Subpart E may be used independently of the provisions in this subpart.

(c) Subpart F of this part governs the issuance of licenses to manufacture nuclear power reactors to be installed and operated at sites not identified in the manufacturing license application. Subpart F may be used independently of the provisions in this subpart. However, an applicant for a manufacturing license under subpart F may reference a design certification.

§ 52.45 Filing of applications.

(a) An application for design certification may be filed notwithstanding the fact that an application for a construction permit, combined license, or manufacturing license for such a facility has not been filed.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and §§ 2.811 through 2.819 of this chapter.

(c) The fees associated with the review of an application for the initial issuance or renewal of a standard design certification are set forth in 10 CFR part 170.

§ 52.46 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (c) and (j).

§ 52.47 Contents of applications; technical information.

The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design certification must include performance requirements and design information sufficiently detailed to permit the

preparation of acceptance and inspection requirements by the NRC, and procurement specifications and construction and installation specifications by an applicant. The Commission will require, before design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination.

(a) The application must contain a final safety analysis report (FSAR) that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and must include the following information:

(1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(2) A description and analysis of the structures, systems, and components (SSCs) of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which these requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that the standard plant will reflect through its design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The description shall be sufficient to permit understanding of the system designs and their relationship to the safety evaluations. Such items as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials; and

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release³ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

³The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem⁴ total effective dose equivalent (TEDE);

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(3) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to 10 CFR part 50, general design criteria (GDC), establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria;

(iii) Information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with an adequate margin for safety;

(4) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal

⁴A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. This dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of emergency core cooling system (ECCS) cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter;

(5) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter;

(6) The information required by § 20.1406 of this chapter;

(7) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(8) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(9) For applications for light-water cooled nuclear power plants, an evaluation of the standard plant design against the NRC's application and review guidance in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the acceptance criteria in the application and review guidance. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding acceptance criteria. The NRC's application and review guidance is not a substitute for the regulations, and compliance is not a requirement.

(10) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e);

(11) Proposed technical specifications prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

(12) An analysis and description of the equipment and systems for combustible gas control as required by 10 CFR 50.44;

(13) The list of electric equipment important to safety that is required by 10 CFR 50.49(d);

(14) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in 10 CFR 50.60 and 50.61;

(15) Information demonstrating how the applicant will comply with requirements for reduction of risk from anticipated transients without scram events in § 50.62;

(16) A coping analysis, and any design features necessary to address station blackout, as required by 10 CFR 50.63;

(17) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 50.68(b)(2)-(b)(4);

(18) A description and analysis of the fire protection design features for the plant necessary to comply with 10 CFR part 50, appendix A, GDC 3, and § 50.48 of this chapter;

(19) A description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the

quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 were satisfied;

(20) The information necessary to demonstrate that the standard plant complies with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(21) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design;

(22) The information necessary to demonstrate how operating experience insights from generic letters and bulletins issued after the most recent revision of the applicable standard review plan and 6 months before the docket date of the application, or comparable international operating experience, have been incorporated into the plant design;

(23) For light-water reactor designs, a description and analysis of design features for the prevention and mitigation of severe accidents, *e.g.*, challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass;

(24) A representative conceptual design for those portions of the plant for which the application does not seek certification, to aid the NRC in its review of the FSAR and to permit assessment of the adequacy of the interface requirements in paragraph (a)(25) of this section;

(25) The interface requirements to be met by those portions of the plant for which the application does not seek certification. These requirements must be sufficiently detailed to allow completion of the FSAR;

(26) Justification that compliance with the interface requirements of paragraph (a)(25) of this section is verifiable through inspections, tests, or analyses. The method to be used for

verification of interface requirements must be included as part of the proposed ITAAC required by paragraph (b)(2) of this section; and

(27) A description of the design-specific probabilistic risk assessment (PRA) and its results.

(b) The application must also contain:

(1) The proposed inspections, tests, analyses, and acceptance criteria (ITAAC) that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a plant that incorporates the design certification is built and will operate in accordance with the design certification, the provisions of the Act, and the Commission's regulations; and

(2) An environmental report as required by 10 CFR 51.55.

(c) This paragraph applies, according to its provisions, to particular applications:

(1) An application for certification of a nuclear power reactor design that is an evolutionary change from light-water reactor designs of plants that have been licensed and in commercial operation before April 18, 1989, must provide an essentially complete nuclear power plant design except for site-specific elements such as the service water intake structure and the ultimate heat sink;

(2) An application for certification of a nuclear power reactor design that differs significantly from the light-water reactor designs described in paragraph (c)(1) of this section or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions must provide an essentially complete nuclear power reactor design except for site-specific elements such as the service water intake structure and the ultimate heat sink, and must meet the requirements of 10 CFR 50.43(e); and

(3) An application for certification of a modular nuclear power reactor design must describe the various options for the configuration of the plant and site, including variations in, or

sharing of, common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the various options, including any restrictions that will be necessary during the construction and startup of a given module to ensure the safe operation of any module already operating.

§ 52.48 Standards for review of applications.

Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR parts 20, 50 and its appendices, 51, 73, and 100.

§ 52.51 Administrative review of applications.

(a) A standard design certification is a rule that will be issued in accordance with the provisions of subpart H of 10 CFR part 2, as supplemented by the provisions of this section. The Commission shall initiate the rulemaking after an application has been filed under § 52.45 and shall specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the *Federal Register* must provide an opportunity for the submission of comments on the proposed design certification rule. If, at the time a proposed design certification rule is published in the *Federal Register* under this paragraph (a), the Commission decides that a legislative hearing should be held, the information required by 10 CFR 2.1502(c) must be included in the *Federal Register* document for the proposed design certification

(b) Following the submission of comments on the proposed design certification rule, the Commission may, at its discretion, hold a legislative hearing under the procedures in subpart O of part 2 of this chapter. The Commission shall publish a document in the *Federal Register* of its decision to hold a legislative hearing. The document shall contain the information specified in paragraph (c) of this section, and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(c) Notwithstanding anything in 10 CFR 2.390 to the contrary, proprietary information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for licenses, provided that the design certification shall be published in Chapter 1 of this title.

§ 52.53 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.54 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 52.51 on an application for a standard design certification and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 52.53, the Commission may issue a standard design certification in the form of a rule for the design which is the subject of the application, if the Commission determines that:

(1) The application meets the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the standard design conforms with the provisions of the Act, and the Commission's regulations;

(4) The applicant is technically qualified;

(5) The proposed inspections, tests, analyses, and acceptance criteria are necessary and sufficient, within the scope of the standard design, to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility

has been constructed and will be operated in accordance with the design certification, the provisions of the Act, and the Commission's regulations;

(6) Issuance of the standard design certification will not be inimical to the common defense and security or to the health and safety of the public;

(7) The findings required by subpart A of part 51 of this chapter have been made; and

(8) The applicant has implemented the quality assurance program described or referenced in the safety analysis report.

(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.

(c) After the Commission has adopted a final design certification rule, the applicant shall not permit any individual to have access to or any facility to possess restricted data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95, as applicable.

§ 52.55 Duration of certification.

(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for 15 years from the date of issuance.

(b) A standard design certification continues to be valid beyond the date of expiration in any proceeding on an application for a combined license or an operating license that references the standard design certification and is docketed either before the date of expiration of the certification, or, if a timely application for renewal of the certification has been filed, before the Commission has determined whether to renew the certification. A design certification also continues to be valid beyond the date of expiration in any hearing held under § 52.103 before operation begins under a combined license that references the design certification.

(c) An applicant for a construction permit or a combined license may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 52.57 Application for renewal.

(a) Not less than 12 nor more than 36 months before the expiration of the initial 15-year period, or any later renewal period, any person may apply for renewal of the certification. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application. The Commission will require, before renewal of certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if this information is necessary for the Commission to make its safety determination. Notice and comment procedures must be used for a rulemaking proceeding on the application for renewal. The Commission, in its discretion, may require the use of additional procedures in individual renewal proceedings.

(b) A design certification, either original or renewed, for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in certain proceedings, in accordance with the provisions of § 52.55.

(c) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.59.

§ 52.59 Criteria for renewal.

(a) The Commission shall issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Atomic Energy Act and the Commission's regulations applicable and in effect at the time the certification was issued.

(b) The Commission may impose other requirements if it determines that:

(1) They are necessary for adequate protection to public health and safety or common defense and security;

(2) They are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the design certification was issued; or

(3) There is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementing those requirements are justified in view of this increased protection.

(c) In addition, the applicant for renewal may request an amendment to the design certification. The Commission shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act and the Commission's regulations in effect at the time of renewal. If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification must be filed in accordance with this subpart.

(d) Denial of renewal does not bar the applicant, or another applicant, from filing a new application for certification of the design, which proposes design changes that correct the deficiencies cited in the denial of the renewal.

§ 52.61 Duration of renewal.

Each renewal of certification for a standard design will be for not less than 10, nor more than 15 years.

§ 52.63 Finality of standard design certifications.

(a)(1) Notwithstanding any provision in 10 CFR 50.109, while a standard design certification rule is in effect under §§ 52.55 or 52.61, the Commission may not modify, rescind, or impose new requirements on the certification information, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that the change:

(i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;

(ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security;

(iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security;

(iv) Provides the detailed design information to be verified under those inspections, tests, analyses, and acceptance criteria (ITAAC) which are directed at certification information (*i.e.*, design acceptance criteria);

(v) Corrects errors in the certification information (*e.g.*, ITAAC, site parameters, and interface requirements); or

(vi) Contributes to increased standardization of the certification information.

(2) The rulemaking procedures for these changes must provide for notice and opportunity for public comment.

(3) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant by action taken under paragraphs (a)(4) or (b)(1) of this section.

(4) The Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing the design certification rule if that part was approved in the design certification while a design certification rule is in effect under § 52.55 or § 52.61, unless:

(i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security; and

(ii) Special circumstances as defined in 10 CFR 52.7 are present. In addition to the factors listed in § 52.7, the Commission shall consider whether the special circumstances which § 52.7 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.

(5) Except as provided in 10 CFR 2.335, in making the findings required for issuance of a combined license, construction permit, operating license, or manufacturing license, or for any hearing under § 52.103, the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b)(1) An applicant or licensee who references a design certification rule may request an exemption from one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 52.7. In addition to the factors listed in § 52.7, the Commission shall consider whether the special circumstances that § 52.7 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an

exemption on request of an applicant must be subject to litigation in the same manner as other issues in the operating license or combined license hearing.

(2) Subject to § 50.59 of this chapter, a licensee who references a design certification rule may make departures from the design of the nuclear power facility, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design. The licensee shall maintain records of all departures from the facility and these records must be maintained and available for audit until the date of termination of the license.

(c) The Commission will require, before granting a construction permit, combined license, operating license, or manufacturing license which references a design certification rule, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

Subpart C – Combined Licenses

§ 52.71 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of combined licenses for nuclear power facilities.

§ 52.73 Relationship to other subparts.

(a) An application for a combined license under this subpart may, but need not, reference a standard design certification, standard design approval, or manufacturing license issued under subparts B, E, or F of this part, respectively, or an early site permit issued under subpart A of this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a design certification is qualified to supply a design, the Commission will entertain an application for a combined license that references a standard design certification issued under subpart B of this part only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

(b) The Commission will require, before granting a combined license that references a standard design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information.

§ 52.75 Filing of applications.

(a) Any person except one excluded by 10 CFR 50.38 may file an application for a combined license for a nuclear power facility with the Director of New Reactors or the Director of Nuclear Reactor Regulation, as appropriate.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR part 170.

§ 52.77 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33.

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) The application must contain a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components of the facility as a whole. The final safety analysis report shall include the following information, at a level of information sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license:

(1)(i) The boundaries of the site;

(ii) The proposed general location of each facility on the site;

(iii) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated;

(iv) The location and description of any nearby industrial, military, or transportation facilities and routes;

(v) The existing and projected future population profile of the area surrounding the site;

(vi) A description and safety assessment of the site on which the facility is to be located.

The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(vi)(A) and (a)(1)(vi)(B) of this section. In performing this assessment, an applicant shall assume a fission product release⁵ from the core into the containment assuming that the facility is operated at the

⁵The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem⁶ total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE; and

(2) A description and analysis of the structures, systems, and components of the facility with emphasis upon performance requirements, the bases, with technical justification therefore, upon which these requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that reactors will reflect through their design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The descriptions shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations. Items as the reactor core, reactor coolant system, instrumentation and control

⁶A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics and proposed operation will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials;

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release⁷ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated;

(3) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter;

(4) The design of the facility including:

⁷The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

(i) The principal design criteria for the facility. Appendix A to part 50 of this chapter, “General Design Criteria for Nuclear Power Plants,” establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria;

(iii) Information relative to materials of construction, arrangement, and dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with adequate margin for safety.

(5) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter;

(6) A description and analysis of the fire protection design features for the reactor necessary to comply with 10 CFR part 50, appendix A, GDC 3, and § 50.48 of this chapter;

(7) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in §§ 50.60 and 50.61 (b)(1) and (b)(2) of this chapter;

- (8) An analysis and description of the equipment and systems for combustible gas control as required by § 50.44 of this chapter;
- (9) The coping analyses, and any design features necessary to address station blackout, as described in § 50.63 of this chapter;
- (10) A description of the program, and its implementation, required by § 50.49(a) of this chapter for the environmental qualification of electric equipment important to safety and the list of electric equipment important to safety that is required by 10 CFR 50.49(d);
- (11) A description of the program(s), and their implementation, necessary to ensure that the systems and components meet the requirements of the ASME Boiler and Pressure Vessel Code and the ASME Code for Operation and Maintenance of Nuclear Power Plants in accordance with 50.55a of this chapter;
- (12) A description of the primary containment leakage rate testing program, and its implementation, necessary to ensure that the containment meets the requirements of appendix J to 10 CFR part 50;
- (13) A description of the reactor vessel material surveillance program required by appendix H to 10 CFR part 50 and its implementation;
- (14) A description of the operator training program, and its implementation, necessary to meet the requirements of 10 CFR part 55;
- (15) A description of the program, and its implementation, for monitoring the effectiveness of maintenance necessary to meet the requirements of § 50.65 of this chapter;
- (16)(i) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, as described in § 50.34a(d) of this chapter;
- (ii) A description of the process and effluent monitoring and sampling program required by appendix I to 10 CFR part 50 and its implementation.

(17) The information with respect to compliance with technically relevant positions of the Three Mile Island requirements in § 50.34(f) of this chapter, with the exception of §§ 50.34(f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(18) If the applicant seeks to use risk-informed treatment of SSCs in accordance with § 50.69 of this chapter, the information required by § 50.69(b)(2) of this chapter;

(19) Information necessary to demonstrate that the plant complies with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(20) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design;

(21) Emergency plans complying with the requirements of § 50.47 of this chapter, and 10 CFR part 50, appendix E;

(22)(i) All emergency plan certifications that have been obtained from the State and local governmental agencies with emergency planning responsibilities must state that:

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency;

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(23) **[RESERVED]**

(24) If the application is for a nuclear power reactor design which differs significantly from light-water reactor designs that were licensed before 1997 or use simplified, inherent, passive, or other innovative means to accomplish their safety functions, the application must describe how the design meets the requirements in § 50.43(e) of this chapter;

(25) A description of the quality assurance program, applied to the design, and to be applied to the fabrication, construction, and testing, of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50 sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant must include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 have been and will be satisfied, including a discussion of how the quality assurance program will be implemented;

(26) The applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements for operation;

(27) Managerial and administrative controls to be used to assure safe operation. Appendix B to 10 CFR part 50 sets forth the requirements for these controls for nuclear power plants. The information on the controls to be used for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 will be satisfied;

(28) Plans for preoperational testing and initial operations;

(29)(i) Plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components;

(ii) Plans for coping with emergencies, other than the plans required by § 52.79(a)(21);

(30) Proposed technical specifications prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

(31) For nuclear power plants to be operated on multi-unit sites, an evaluation of the potential hazards to the structures, systems, and components important to safety of operating

units resulting from construction activities, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation are not exceeded as a result of construction activities at the multi-unit sites;

(32) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(33) A description of the training program required by § 50.120 of this chapter and its implementation;

(34) A description and plans for implementation of an operator requalification program. The operator requalification program must as a minimum, meet the requirements for those programs contained in § 55.59 of this chapter;

(35)(i) A physical security plan, describing how the applicant will meet the requirements of 10 CFR part 73 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable;

(ii) A description of the implementation of the physical security plan;

(36)(i) A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license shall include the information contained in the applicant's safeguards contingency plan.⁸ (Implementing procedures required for this plan need not be submitted for approval.)

⁸A physical security plan that contains all the information required in both § 73.55 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

(ii) A training and qualification plan in accordance with the criteria set forth in appendix B to 10 CFR part 73.

(iii) A description of the implementation of the safeguards contingency plan and the training and qualification plan;

(iv) Each applicant who prepares a physical security plan, a safeguards contingency plan, or a guard qualification and training plan, shall protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of § 73.21 of this chapter, as appropriate.

(37) The information necessary to demonstrate how operating experience insights from generic letters and bulletins issued after the most recent revision of the applicable standard review plan and 6 months before the docket date of the application, or comparable international operating experience, have been incorporated into the plant design;

(38) For light-water reactor designs, a description and analysis of design features for the prevention and mitigation of severe accidents, *e.g.*, challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass;

(39) A description of the radiation protection program required by § 20.1101 of this chapter and its implementation.

(40) A description of the fire protection program required by § 50.48 of this chapter and its implementation.

(41) For applications for light-water cooled nuclear power plant combined licenses, an evaluation of the facility against the NRC's application and review guidance in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for a facility and those corresponding features, techniques, and

measures given in the acceptance criteria in the application and review guidance. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding acceptance criteria. The NRC's application and review guidance is not a substitute for the regulations, and compliance is not a requirement;

(42) Information demonstrating how the applicant will comply with requirements for reduction of risk from anticipated transients without scram (ATWS) events in § 50.62 of this chapter;

(43) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 50.68 of this chapter;

(44) A description of the fitness-for-duty program required by 10 CFR part 26 and its implementation.

(45) The information required by § 20.1406 of this chapter.

(46) A description of the plant-specific probabilistic risk assessment (PRA) and its results.

(b) If the combined license application references an early site permit, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the early site permit, *provided, however*, that the final safety analysis report must either include or incorporate by reference the early site permit site safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the final safety analysis report does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application shall include a request for a variance that complies with the requirements of §§ 52.39 and 52.93.

(3) The final safety analysis report must demonstrate that all terms and conditions that have been included in the early site permit, other than those imposed under § 50.36b, will be satisfied by the date of issuance of the combined license. Any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the final safety analysis report must include any new or additional information that updates and corrects the information that was provided under § 52.17(b), and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a decrease in effectiveness under § 50.54(q) of this chapter.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(22) of this section are not required.

(c) If the combined license application references a standard design approval, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the design approval, *provided, however*, that the final safety analysis report must either include or incorporate by reference the standard design approval final safety analysis report and must contain, in addition to the information and

analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific PRA information must use the PRA information for the design approval and must be updated to account for site-specific design information and any design changes or departures.

(2) The final safety analysis report must demonstrate that all terms and conditions that have been included in the final design approval will be satisfied by the date of issuance of the combined license.

(d) If the combined license application references a standard design certification, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the design certification, *provided, however*, that the final safety analysis report must either include or incorporate by reference the standard design certification final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the design certification. In addition, the plant-specific PRA information must use the PRA information for the design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The final safety analysis report must demonstrate that the interface requirements established for the design under § 52.47 have been met.

(3) The final safety analysis report must demonstrate that all requirements and restrictions set forth in the referenced design certification rule, other than those imposed under § 50.36b, must be satisfied by the date of issuance of the combined license. Any requirements and restrictions set forth in the referenced design certification rule that could not be satisfied by

the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(e) If the combined license application references the use of one or more manufactured nuclear power reactors licensed under subpart F of this part, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the manufacturing license, *provided, however*, that the final safety analysis report must either include or incorporate by reference the manufacturing license final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the manufacturing license. In addition, the plant-specific PRA information must use the PRA information for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures.

(2) The final safety analysis report must demonstrate that the interface requirements established for the design have been met.

(3) The final safety analysis report must demonstrate that all terms and conditions that have been included in the manufacturing license, other than those imposed under § 50.36b, will be satisfied by the date of issuance of the combined license. Any terms or conditions of the manufacturing license that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

§ 52.80 Contents of applications; additional technical information.

The application must contain:

(a) The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria which are

necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the combined license, the provisions of the Atomic Energy Act, and the NRC's regulations.

(1) If the application references an early site permit with ITAAC, the early site permit ITAAC must apply to those aspects of the combined license which are approved in the early site permit.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are approved in the design certification.

(3) If the application references an early site permit with ITAAC or a standard design certification or both, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 52.85 must indicate that the application includes this notification.

(b) A complete environmental report as required by 10 CFR 51.50(c).

(c) If the applicant wishes to be able to perform the activities at the site allowed by 10 CFR 50.10(e) before issuance of the combined license, the applicant must identify and describe the activities that are requested and propose a plan for redress of the site in the event that the activities are performed and either construction is abandoned or the combined license is revoked. The application must demonstrate that there is reasonable assurance that redress carried out under the plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

§ 52.81 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 50, 51, 54, 55, 73, 100, and 140.

§ 52.83 Finality of referenced NRC approvals; partial initial decision on site suitability.

(a) If the application for a combined license under this subpart references an early site permit, design certification rule, standard design approval, or manufacturing license, the scope and nature of matters resolved for the application and any combined licensed issued are governed by the relevant provisions addressing finality, including §§ 52.39, 52.63, 52.98, 52.145, and 52.171.

(b) While a partial decision on site suitability is in effect under 10 CFR 2.617(b)(2), the scope and nature of matters resolved in the proceeding are governed by the finality provisions in 10 CFR 2.629.

§ 52.85 Administrative review of applications; hearings.

A proceeding on a combined license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing. All hearings on combined licenses are governed by the procedures contained in 10 CFR part 2.

§ 52.87 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application that concern safety and shall apply the standards referenced in § 52.81, in accordance with the finality provisions in § 52.83.

§ 52.89 [RESERVED]

§ 52.91 Authorization to conduct site activities.

(a) If the application does not reference an early site permit which authorizes the applicant to perform site preparation activities, the applicant may not perform the site preparation activities allowed by 10 CFR 50.10(e)(1) without obtaining the separate authorization required by 10 CFR 50.10(e)(1). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by 10 CFR 50.10(e)(2) and has determined that there is reasonable assurance that redress carried out under the site redress plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

(b) Authorization to conduct the activities described in 10 CFR 50.10(e)(3)(i) may be granted only after the presiding officer in the combined license proceeding makes the additional finding required by 10 CFR 50.10(e)(3)(ii).

(c) If, after an applicant for a combined license has performed the activities permitted by paragraph (a) or (b) of this section, and the application for the license is withdrawn or denied, then the applicant shall redress the site in accord with the terms of the site redress plan. If a use not envisaged in the redress plan is found for the site or parts before redress is complete, the applicant shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 52.93 Exemptions and variances.

(a) Applicants for a combined license under this subpart, or any amendment to a combined license, may include in the application a request for an exemption from one or more of the Commission's regulations.

(1) If the request is for an exemption from any part of a referenced design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced design certification rule, or with § 52.63 if there are no applicable exemption provisions in the referenced design certification rule.

(2) For all other requests for exemptions, the Commission may grant a request if it determines that the exemption complies with § 52.7.

(b) An applicant for a combined license who has filed an application referencing an early site permit issued under subpart A of this part may include in the application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the permit, or from the site safety analysis report. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Once a construction permit or combined license referencing an early site permit is issued, variances from the early site permit will not be granted for that construction permit or combined license.

(c) An applicant for a combined license who has filed an application referencing a nuclear power reactor manufactured under a manufacturing license issued under subpart F of this part may include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of 10 CFR 52.7, and that the special circumstances outweigh any

decrease in safety that may result from the reduction in standardization caused by the departure.

(d) Issuance of a variance under paragraph (b) or a departure under paragraph (c) of this section is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

§ 52.97 Issuance of combined licenses.

(a)(1) After conducting a hearing in accordance with § 52.85 and receiving the report submitted by the ACRS, the Commission may issue a combined license if the Commission finds that:

- (i) The applicable standards and requirements of the Act and the Commission's regulations have been met;
- (ii) Any required notifications to other agencies or bodies have been duly made;
- (iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations.
- (iv) The applicant is technically and financially qualified to engage in the activities authorized; and
- (v) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and
- (vi) The findings required by subpart A of part 51 of this chapter have been made.

(2) The Commission may also find, at the time it issues the combined license, that certain acceptance criteria in one or more of the inspections, tests, analyses, and acceptance criteria (ITAAC) in a referenced early site permit or standard design certification have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance

criteria will be deemed to be excluded from the combined license, and findings under § 52.103(g) with respect to those acceptance criteria are unnecessary.

(b) The Commission shall identify within the combined license the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations.

(c) A combined license shall contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

§ 52.98 Finality of combined licenses; information requests.

(a) After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of § 52.103 or § 50.109 of this chapter, as applicable.

(b) If the combined license does not reference a design certification or a reactor manufactured under a subpart F of this part manufacturing license, then a licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) under the applicable change processes in 10 CFR part 50 (e.g., §§ 50.54, 50.59, or 50.90 of this chapter).

(c) If the combined license references a certified design, then—

(1) Changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule; and

(2) Changes that are not within the scope of the referenced design certification rule are subject to the applicable change processes in 10 CFR part 50, unless they also involve changes to or noncompliance with information within the scope of the referenced design certification rule. In these cases, the applicable provisions of this section and the design certification rule apply.

(d) If the combined license references a reactor manufactured under a subpart F of this part manufacturing license, then-

(1) Changes to or departures from information within the scope of the manufactured reactor's design are subject to the change processes in § 52.171; and

(2) Changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in 10 CFR part 50.

(e) The Commission may issue and make immediately effective any amendment to a combined license upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed in accordance with the procedures specified in 10 CFR 50.91.

(f) Any modification to, addition to, or deletion from the terms and conditions of a combined license, including any modification to, addition to, or deletion from the inspections, tests, analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

(g) Except for information sought to verify licensee compliance with the current licensing basis for that facility, information requests to the holder of a combined license must be

evaluated before issuance to ensure that the burden to be imposed on the licensee is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.99 Inspection during construction.

(a) The licensee shall submit to the NRC, no later than 1 year after issuance of the combined license, its detailed schedule for completing the inspections, tests, or analyses in the ITAAC. The licensee shall submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, the licensee shall submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (c)(1) of this section.

(b) With respect to activities subject to an ITAAC, an applicant for a combined license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and pre-operational activities, even though the NRC may not have found that any particular ITAAC has been met.

(c)(1) The licensee shall notify the NRC that the inspections, tests, or analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met. The notification must contain sufficient information to demonstrate that the inspections, tests, or analyses have been successfully completed and that the acceptance criteria have been met.

(2) If the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee shall notify the NRC that the inspections, tests, or analyses for all

uncompleted ITAAC will be successfully completed and all acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the inspections, tests, or analyses will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met.

(d)(1) In the event that an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under § 52.98(f).

(2) In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under § 52.98(f).

(e) The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed.

(1) At appropriate intervals until the last date for submission of requests for hearing under § 52.103(a), the NRC shall publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC shall make publicly available the licensee notifications under paragraph (c)(1), and, no later than the date of publication of the notice of intended operation required by § 52.103(a), make available all licensee notifications under paragraphs (c)(1) and (c)(2) of this section.

§ 52.103 Operation under a combined license.

(a) The licensee shall notify the NRC of its scheduled date for initial loading of fuel no later than 270 days before the scheduled date and shall notify the NRC of updates to its schedule every 30 days thereafter. Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a combined license under this part, the Commission shall publish notice of intended operation in the *Federal Register*. The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the combined license, except that a hearing shall not be granted for those ITAAC which the Commission found were met under § 52.97(a)(2).

(b) A request for hearing under paragraph (a) of this section must show, *prima facie*, that—

(1) One or more of the acceptance criteria of the ITAAC in the combined license have not been, or will not be met; and

(2) The specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(c) After receiving a request for a hearing, the Commission expeditiously shall either deny or grant the request. If the request is granted, the Commission shall determine, after considering petitioners' *prima facie* showing and any answers thereto, whether during a period of interim operation, there will be reasonable assurance of adequate protection of the public health and safety. If the Commission determines that there is reasonable assurance, it shall allow operation during an interim period under the combined license.

(d) The Commission, in its discretion, shall determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and shall state its reasons therefore.

(e) The Commission shall, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or by the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the combined license will be processed as a request for action in accordance with 10 CFR 2.206. The petitioner shall file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the Commission shall determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the combined license will not be affected by the granting of the petition unless the order is made immediately effective.

(g) The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 52.97(a)(2). If the combined license is for a modular design, each reactor module may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the combined license, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (a) of this section, all ITAAC expire upon final Commission action in the proceeding. However, subsequent changes to the facility or procedures described in the final safety analysis report (as updated) must comply with the requirements in §§ 52.98(e) or (f), as applicable.

§ 52.104 Duration of combined license.

A combined license is issued for a specified period not to exceed 40 years from the date on which the Commission makes a finding that acceptance criteria are met under § 52.103(g) or allowing operation during an interim period under the combined license under § 52.103(c).

§ 52.105 Transfer of combined license.

A combined license may be transferred in accordance with § 50.80 of this chapter.

§ 52.107 Application for renewal.

The filing of an application for a renewed license must be in accordance with 10 CFR part 54.

§ 52.109 Continuation of combined license.

Each combined license for a facility that has permanently ceased operations, continues in effect beyond the expiration date to authorize ownership and possession of the production or utilization facility, until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness the licensee shall—

(1) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(2) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the combined license for the facility.

§ 52.110 Termination of license.

(a)(1) When a licensee has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 52.3(b)(8);

(2) Once fuel has been permanently removed from the reactor vessel, the licensee shall submit a written certification to the NRC that meets the requirements of § 52.3(b)(9); and

(3) For licensees whose licenses have been permanently modified to allow possession but not operation of the facility, before [insert the effective date of this rule], the certification required in paragraph (a)(1) of this section shall be deemed to have been submitted.

(b) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the 10 CFR part 52 license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel.

(c) Decommissioning will be completed within 60 years of permanent cessation of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site-specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.

(d)(1) Before or within 2 years following permanent cessation of operations, the licensee shall submit a post-shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The report must include a description of the planned decommissioning activities along with a schedule for their accomplishment, an estimate of expected costs, and a discussion that provides the reasons for concluding that the

environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements.

(2) The NRC shall notice receipt of the PSDAR and make the PSDAR available for public comment. The NRC shall also schedule a public meeting in the vicinity of the licensee's facility upon receipt of the PSDAR. The NRC shall publish a document in the *Federal Register* and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time and location of the meeting, along with a brief description of the purpose of the meeting.

(e) Licensees shall not perform any major decommissioning activities, as defined in § 50.2 of this chapter, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel, as required under § 52.110(a)(1), have been submitted.

(f) Licensees shall not perform any decommissioning activities, as defined in § 52.1, that—

- (1) Foreclose release of the site for possible unrestricted use;
- (2) Result in significant environmental impacts not previously reviewed; or
- (3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(g) In taking actions permitted under § 50.59 of this chapter following submittal of the PSDAR, the licensee shall notify the NRC in writing and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that significantly increase the decommissioning cost.

(h)(1) Decommissioning trust funds may be used by licensees if—

(i) The withdrawals are for expenses for legitimate decommissioning activities consistent with the definition of decommissioning in § 52.1;

(ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise and;

(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(2) Initially, 3 percent of the generic amount specified in § 50.75 of this chapter may be used for decommissioning planning. For licensees that have submitted the certifications required under § 52.110(a) and commencing 90 days after the NRC has received the PSDAR, an additional 20 percent may be used. A site-specific decommissioning cost estimate must be submitted to the NRC before the licensee may use any funding in excess of these amounts.

(3) Within 2 years following permanent cessation of operations, if not already submitted, the licensee shall submit a site-specific decommissioning cost estimate.

(4) For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee shall provide a means of adjusting cost estimates and associated funding levels over the storage or surveillance period.

(i) All power reactor licensees must submit an application for termination of license. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(1) The license termination plan must be a supplement to the FSAR or equivalent and must be submitted at least 2 years before termination of the license date.

(2) The license termination plan must include—

(i) A site characterization;

- (ii) Identification of remaining dismantlement activities;
- (iii) Plans for site remediation;
- (iv) Detailed plans for the final radiation survey;
- (v) A description of the end use of the site, if restricted;
- (vi) An updated site-specific estimate of remaining decommissioning costs;
- (vii) A supplement to the environmental report, under § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

- (viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.

(3) The NRC shall notice receipt of the license termination plan and make the license termination plan available for public comment. The NRC shall also schedule a public meeting in the vicinity of the licensee's facility upon receipt of the license termination plan. The NRC shall publish a document in the *Federal Register* and in a forum, such as local newspapers, which is readily accessible to individuals in the vicinity of the site, announcing the date, time and location of the meeting, along with a brief description of the purpose of the meeting.

(j) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission shall approve the plan, by license amendment, subject to terms and conditions as it deems appropriate and necessary and authorize implementation of the license termination plan.

(k) The Commission shall terminate the license if it determines that—

(1) The remaining dismantlement has been performed in accordance with the approved license termination plan; and

(2) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in subpart E to 10 CFR part 20.

(l) For a facility that has permanently ceased operation before the expiration of its license, the collection period for any shortfall of funds will be determined, upon application by the licensee, on a case-by-case basis taking into account the specific financial situation of each licensee.

Subpart D – RESERVED

Subpart E - Standard Design Approvals

§ 52.131 Scope of subpart.

This subpart sets out procedures for the filing, NRC staff review, and referral to the Advisory Committee on Reactor Safeguards of standard designs for a nuclear power reactor of the type described in § 50.22 of this chapter or major portions thereof.

§ 52.133 Relationship to other subparts.

(a) This subpart applies to a person that requests a standard design approval from the NRC staff separately from an application for a construction permit filed under 10 CFR part 50 or

a combined license filed under subpart C of this part. An applicant for a construction permit or combined license may reference a standard design approval.

(b) Subpart B of this part governs the certification by rulemaking of the design of a nuclear power plant. Subpart B may be used independently of the provisions in this subpart.

(c) Subpart F of this part governs the issuance of licenses to manufacture nuclear power reactors to be installed and operated at sites not identified in the manufacturing license application. Subpart F of this part may be used independently of the provisions in this subpart.

§ 52.135 Filing of applications.

(a) Any person may submit a proposed standard design for a nuclear power reactor of the type described in 10 CFR 50.22 to the NRC staff for its review. The submittal may consist of either the final design for the entire facility or the final design of major portions thereof.

(b) The submittal for review of the proposed standard design must be made in the same manner and in the same number of copies as provided in 10 CFR 50.30 and 52.3 for license applications.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR part 170.

§ 52.136 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (d) and (j).

§ 52.137 Contents of applications; technical information.

If the applicant seeks review of a major portion of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought.

(a) The application must contain a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility, or major portion thereof, and must include the following information:

(1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(2) A description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the bases, with technical justification, upon which the requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that the standard plant will reflect through its design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The description shall be sufficient to permit understanding of the system designs and their relationship to the safety evaluations. Items such as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials; and

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release⁹ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem¹⁰ total effective dose equivalent (TEDE); and

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release

⁹The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

¹⁰A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

(during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(3) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to 10 CFR part 50, general design criteria (GDC), establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria; and

(iii) Information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with adequate margin for safety;

(4) An analysis and evaluation of the design and performance of SSC with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of 10 CFR 50.46 and 50.46a;

(5) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter;

(6) The information required by § 20.1406 of this chapter;

(7) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(8) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v) of 10 CFR 50.34(f);

(9) For applications for light-water cooled nuclear power plants, an evaluation of the standard plant design against the NRC's application and review guidance in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding acceptance criteria in the application and review guidance. The NRC's application and review guidance is not a substitute for the regulations, and compliance is not a requirement;

(10) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e);

(11) The information pertaining to design features that affect plans for coping with emergencies in the operation of the reactor facility or a major portion thereof;

(12) An analysis and description of the equipment and systems for combustible gas control as required by § 50.44 of this chapter;

(13) The list of electric equipment important to safety that is required by 10 CFR 50.49(d);

(14) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in 10 CFR 50.60 and 50.61;

(15) Information demonstrating how the applicant will comply with requirements for reduction of risk from anticipated transients without scram (ATWS) events in § 50.62;

(16) The coping analysis, and any design features necessary to address station blackout, as described in § 50.63 of this chapter;

(17) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 50.68(b)(2)-(b)(4);

(18) A description and analysis of the fire protection design features for the standard plant necessary to comply with part 50, appendix A, GDC 3, and § 50.48 of this chapter;

(19) A description of the quality assurance program applied to the design of the SSCs of the facility. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 were satisfied;

(20) The information necessary to demonstrate that the standard plant complies with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(21) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design;

(22) The information necessary to demonstrate how operating experience insights from generic letters and bulletins issued after the most recent revision of the applicable standard

review plan and 6 months before the docket date of the application, or comparable international operating experience, have been incorporated into the plant design;

(23) For light-water reactor designs, a description and analysis of design features for the prevention and mitigation of severe accidents, *e.g.*, challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass;

(24) A description, analysis, and evaluation of the interfaces between the standard design and the balance of the nuclear power plant; and

(25) A description of the design-specific probabilistic risk assessment and its results.

(b) An application for approval of a standard design, which differs significantly from the light-water reactor designs of plants that have been licensed and in commercial operation before April 18, 1989, or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions, must meet the requirements of 10 CFR 50.43(e).

(c) An application for approval of a standard design, which differs significantly from the light-water reactor designs of plants that have been licensed and in commercial operation before April 18, 1989, or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions, must meet the requirements of 10 CFR 50.43(e).

§ 52.139 Standards for review of applications.

Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR parts 20, 50 and its appendices, and 10 CFR parts 73 and 100.

§ 52.141 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.143 Staff approval of design.

Upon completion of its review of a submittal under this subpart and receipt of a report by the Advisory Committee on Reactor Safeguards under § 52.141 of this subpart, the NRC staff shall publish a determination in the *Federal Register* as to whether or not the design is acceptable, subject to appropriate terms and conditions, and make an analysis of the design in the form of a report available at the NRC Web site, <http://www.nrc.gov>.

§ 52.145 Finality of standard design approvals; information requests.

(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their review of any individual facility license application that incorporates by reference a standard design approved in accordance with this paragraph unless there exists significant new information that substantially affects the earlier determination or other good cause.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under part 2 of this chapter.

(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.147 Duration of design approval.

A standard design approval issued under this subpart is valid for 15 years from the date of issuance and may not be renewed. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a construction permit or an operating license under part 50 or a combined license or manufacturing license under part 52 that references the final design approval and is docketed before the date of expiration of the design approval.

Subpart F – Manufacturing Licenses

§ 52.151 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of a license authorizing manufacture of nuclear power reactors to be installed at sites not identified in the manufacturing license application.

§ 52.153 Relationship to other subparts.

(a) A nuclear power reactor manufactured under a manufacturing license issued under this subpart may only be transported to and installed at a site for which either a construction permit under part 50 of this chapter or a combined license under subpart C of this part has been issued.

(b) Subpart B of this part governs the certification by rulemaking of the design of standard nuclear power facilities. Subpart E of this part governs the NRC staff review and approval of standard designs for a nuclear power facility. A manufacturing license applicant may reference a standard design certification or a standard design approval in its application. These subparts may also be used independently of the provisions in this subpart.

§ 52.155 Filing of applications.

(a) Any person, except one excluded by 10 CFR 50.38, may file an application for a manufacturing license under this subpart with the Director of New Reactors or the Director of Nuclear Reactor Regulation, as appropriate.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR part 170.

52.156 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (d), and (j).

§ 52.157 Contents of applications; technical information in final safety analysis report.

The application must contain a final safety analysis report containing the information set forth below, with a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that the manufacturing conforms to the design and to reach a final conclusion on all safety questions associated with the design, permit the preparation of construction and installation specifications by an applicant who seeks to use the manufactured reactor, and permit the preparation of acceptance and inspection requirements by the NRC:

(a) The principal design criteria for the reactor to be manufactured. Appendix A of 10 CFR part 50, "General Design Criteria for Nuclear Power Plants," establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in

design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(b) The design bases and the relation of the design bases to the principal design criteria;

(c) A description and analysis of the structures, systems, and components of the reactor to be manufactured, with emphasis upon the materials of manufacture, performance requirements, the bases, with technical justification therefor, upon which the performance requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations. Items such as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

(1) Intended use of the manufactured reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(2) The extent to which generally accepted engineering standards are applied to the design of the reactor; and

(3) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials;

(d) The safety features that are engineered into the reactor and those barriers that must be breached as a result of an accident before a release of radioactive material to the

environment can occur. Special attention must be directed to reactor design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release¹¹ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(1) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem¹² total effective dose equivalent (TEDE);

(2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE; and

(e) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter.

¹¹The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

¹²A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

(f) Information necessary to establish that the design of the reactor to be manufactured complies with the technical requirements in 10 CFR Chapter 1, including:

(1) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter;

(2) A description and analysis of the fire protection design features for the reactor necessary to comply with 10 CFR part 50, appendix A, GDC 3 and § 50.48 of this chapter;

(3) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in §§ 50.60 and 50.61 of this chapter;

(4) An analysis and description of the equipment and systems for combustible gas control as required by § 50.44 of this chapter;

(5) The coping analysis, and any design features necessary to address station blackout, as described in § 50.63 of this chapter;

(6) The list of electric equipment important to safety that is required by 10 CFR 50.49(d);

(7) Information demonstrating how the applicant will comply with requirements for reduction of risk from anticipated transients without scram (ATWS) events in § 50.62;

(8) Information demonstrating how the applicant will comply with requirements for criticality accidents in § 50.68(b)(2)-(b)(4);

(9) The information required by § 20.1406 of this chapter;

(10) **[RESERVED]**

(11) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, as described in § 50.34a(e) of this chapter;

(12) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in § 50.34(f) of this chapter, except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(13) If the applicant seeks to use risk-informed treatment of SSCs in accordance with § 50.69 of this chapter, the information required by § 50.69(b)(2) of this chapter;

(14) The information necessary to demonstrate that the manufactured reactor complies with the earthquake engineering criteria in appendix S to 10 CFR part 50;

(15) Information sufficient to demonstrate compliance with the applicable requirements regarding testing, analysis, and prototypes as set forth in § 50.43(e) of this chapter;

(16) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(17) A description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program must include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 have been and will be satisfied; and

(18) Proposed technical specifications applicable to the reactor being manufactured, prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

(19) The site parameters postulated for the design, and an analysis and evaluation of the reactor design in terms of those site parameters;

(20) The interface requirements between the manufactured reactor and the remaining portions of the nuclear power plant. These requirements must be sufficiently detailed to allow for completion of the final safety analysis;

(21) Justification that compliance with the interface requirements of paragraph (f)(20) of this section is verifiable through inspections, testing, or analysis. The method to be used for verification of interface requirements must be included as part of the proposed ITAAC required by § 52.158(b);

(22) A representative conceptual design for a nuclear power facility using the manufactured reactor, to aid the NRC in its review of the final safety analysis required by this section and to permit assessment of the adequacy of the interface requirements in paragraph (f)(20) of this section;

(23) For light-water reactor designs, a description and analysis of design features for the prevention and mitigation of severe accidents, *e.g.*, challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass;

(24) **[RESERVED]**;

(25) If the reactor is to be used in modular plant design, a description of the various options for the configuration of the plant and site, including variations in, or sharing of, common systems, interface requirements, and system interactions. The final safety analysis must account for differences among the various options, including any restrictions that will be necessary during the construction and startup of a given module to ensure the safe operation of any module already operating;

(26) A description of the management plan for design and manufacturing activities, including:

(i) The organizational and management structure singularly responsible for direction of design and manufacture of the reactor;

(ii) Technical resources directed by the applicant, and the qualifications requirements;

(iii) Details of the interaction of design and manufacture within the applicant's organization and the manner by which the applicant will ensure close integration of the architect engineer and the nuclear steam supply vendor, as applicable;

(iv) Proposed procedures governing the preparation of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and verifying the condition of the manufactured reactor upon receipt at the site; and

(v) The degree of top level management oversight and technical control to be exercised by the applicant during design and manufacture, including the preparation and implementation of procedures necessary to guide the effort;

(27) Necessary parameters to be used in developing plans for preoperational testing and initial operation;

(28) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application and which are technically relevant to the design;

(29) The information necessary to demonstrate how operating experience insights from generic letters and bulletins issued after the most recent revision of the applicable standard review plan and 6 months before application, or comparable international operating experience, have been incorporated into the manufactured reactor design;

(30) For applications for light-water cooled nuclear power plants, an evaluation of the design to be manufactured against the NRC's application and review guidance in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the acceptance criteria in the application and review guidance. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding acceptance criteria. The NRC's application and review guidance is not a substitute for the regulations, and compliance is not a requirement.

(31) A description of the design-specific probabilistic risk assessment and its results.

§ 52.158 Contents of application; additional technical information.

The application must contain:

(a)(1) *Inspections, tests, analyses, and acceptance criteria (ITAAC)*. The proposed inspections, tests and analyses that the licensee who will be operating the reactor shall perform, and the acceptance criteria which are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met:

(i) The reactor has been manufactured in conformance with the manufacturing license; the provisions of the Atomic Energy Act, and the Commission's regulations; and

(ii) The manufactured reactor will operate in conformity with the approved design and any license authorizing operation of the manufactured reactor.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 52.163 must indicate that the application includes this notification.

(b)(1) An environmental report as required by 10 CFR 51.54.

(2) If the manufacturing license application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the reactor.

§ 52.159 Standards for review of application.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR parts 20, 50 and its appendices, 51, 73, and 100 and its appendices.

§ 52.161 [RESERVED]

§ 52.163 Administrative review of applications; hearings.

A proceeding on a manufacturing license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of

proposed action in § 2.105 of this chapter, *provided, however*, that the designated sections may not be construed to require that the environmental report or draft or final environmental impact statement include an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources. All hearings on manufacturing licenses are governed by the hearing procedures contained in 10 CFR part 2, subparts C, G, L, and N.

§ 52.165 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.167 Issuance of manufacturing license.

(a) After conducting a hearing in accordance with § 52.163 and receiving the report submitted by the ACRS, the Commission may issue a manufacturing license if the Commission finds that:

(1) Applicable standards and requirements of the Act and the Commission's regulations have been met;

(2) There is reasonable assurance that the reactor(s) will be manufactured, and can be transported, incorporated into a nuclear power plant, and operated in conformity with the manufacturing license, the provision of the Act, and the Commission's regulations;

(3) The proposed reactor(s) can be incorporated into a nuclear power plant and operated at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactor(s) without undue risk to the health and safety of the public;

(4) The applicant is technically qualified to design and manufacture the proposed nuclear power reactor(s);

(5) The proposed inspections, tests, analyses and acceptance criteria are necessary and sufficient, within the scope of the manufacturing license, to provide reasonable assurance that the manufactured reactor has been manufactured and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public; and

(7) The findings required by subpart A of part 51 of this chapter have been made.

(b) Each manufacturing license issued under this subpart shall specify:

(1) Terms and conditions as the Commission deems necessary and appropriate;

(2) Technical specifications for operation of the manufactured reactor, as the Commission deems necessary and appropriate;

(3) Site parameters and design characteristics for the manufactured reactor; and

(4) The interface requirements to be met by the site-specific elements of the facility, such as the service water intake structure and the ultimate heat sink, not within the scope of the manufactured reactor.

(c)(1) A holder of a manufacturing license may not transport or allow to be removed from the place of manufacture the manufactured reactor except to the site of a licensee with a either a construction permit under part 50 of this chapter or a combined license under subpart C of this part. The construction permit or combined license must authorize the construction of a nuclear power facility using the manufactured reactor(s).

(2) A holder of a manufacturing license shall include, in any contract governing the transport of a manufactured reactor from the place of manufacture to any other location, a provision requiring that the person or entity transporting the manufactured reactor to comply with all NRC-approved shipping requirements in the manufacturing license.

§ 52.169 [Reserved]

§ 52.171 Finality of manufacturing licenses; information requests.

(a)(1) Notwithstanding any provision in 10 CFR 50.109, during the term of a manufacturing license the Commission may not modify, rescind, or impose new requirements on the design of the nuclear power reactor being manufactured, or the requirements for the manufacture of the nuclear power reactor, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

(2) Any modification to the design of a manufactured nuclear power reactor which is imposed by the Commission under paragraph (a)(1) of this section will be applied to all reactors manufactured under the license, including those that have already been transported and sited, except those reactors to which the modification has been rendered technically irrelevant by action taken under paragraph (b) of this section.

(3) In making the findings required for issuance of a construction permit, operating license, combined license, in any hearing under § 52.103, or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, for which a nuclear power reactor manufactured under this subpart is referenced or used, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the manufacturing license, including the adequacy of design of the manufactured reactor, the costs and benefits of SAMDAs, and the bases for not incorporating SAMDAs into the design of the reactor to be manufactured.

(b)(1) The holder of a manufacturing license may not make changes to the design of the nuclear power reactor authorized to be manufactured without prior Commission approval. The request for a change to the design must be in the form of an application for a license amendment, and must meet the requirements of 10 CFR 50.90 and 50.92.

(2) An applicant or licensee who references or uses a nuclear power reactor manufactured under a manufacturing license under this subpart may request a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of 10 CFR 52.7, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The granting of a departure on request of an applicant must be subject to litigation in the same manner as other issues in the construction permit or combined license hearing.

(c) Except for information requests seeking to verify compliance with the current licensing basis of either the manufacturing license or the manufactured reactor, information requests to the holder of a manufacturing license or an applicant or licensee using a manufactured reactor must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.173 Duration of manufacturing license.

A manufacturing license issued under this subpart may be valid for not less than 5, nor more than 15 years from the date of issuance. A holder of a manufacturing license may not

initiate the manufacture of a reactor less than 3 years before the expiration of the license even though a timely application for renewal has been docketed with the NRC. Upon expiration of the manufacturing license, the manufacture of any uncompleted reactors must cease unless a timely application for renewal has been docketed with the NRC.

§ 52.175 Transfer of manufacturing license.

A manufacturing license may be transferred in accordance with § 50.80 of this chapter.

§ 52.177 Application for renewal.

(a) Not less than 12 months, nor more than 5 years before the expiration of the manufacturing license, or any later renewal period, the holder of the manufacturing license may apply for a renewal of the license. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(b) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and 10 CFR 52.3 and 50.30.

(c) A manufacturing license, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has made a final determination on the renewal application, *provided, however*, that in accordance with § 52.173, the holder of a manufacturing license may not begin manufacture of a reactor less than 3 years before the expiration of the license.

(d) Any person whose interest may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR 2.309. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.104.

(e) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.159.

§ 52.179 Criteria for renewal.

The Commission may grant the renewal if the Commission determines:

(a) The manufacturing license complies with the Atomic Energy Act and the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; and

(b) Any new requirements the Commission may wish to impose are:

(1) Necessary for adequate protection to public health and safety or common defense and security;

(2) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; or

(3) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

§ 52.181 Duration of renewal.

A renewed manufacturing license may be issued for a term of not less than 5, nor more than 15 years, plus any remaining years on the manufacturing license then in effect before renewal. The renewed license shall be subject to the requirements of §§ 52.171 and 52.175.

Subpart G – [RESERVED]

Subpart H – Enforcement

§ 52.301 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974, as amended; or
- (3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

- (1) For violations of—
 - (i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;
 - (ii) Section 206 of the Energy Reorganization Act;
 - (iii) Any regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;
 - (iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.
- (2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 52.303 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under Sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in part 52 are issued under one or more of Sections 161b, 161i, or 160o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 52 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 52.0, 52.1, 52.2, 52.3, 52.7, 52.8, 52.9, 52.10, 52.11, 52.12, 52.13, 52.15, 52.16, 52.17, 52.18, 52.21, 52.23, 52.24, 52.27, 52.28, 52.29, 52.31, 52.33, 52.39, 52.41, 52.43, 52.45, 52.46, 52.47, 52.48, 52.51, 52.53, 52.54, 52.55, 52.57, 52.59, 52.61, 52.63, 52.71, 52.73, 52.75, 52.77, 52.79, 52.80, 52.81, 52.83, 52.85, 52.87, 52.93, 52.97, 52.98, 52.103, 52.104, 52.105, 52.107, 52.109, 52.131, 52.133, 52.135, 52.136, 52.137, 52.139, 52.141, 52.143, 52.145, 52.147, 52.151, 52.153, 52.155, 52.156, 52.157, 52.158, 52.159, 52.161, 52.163, 52.165, 52.167, 52.171, 52.173, 52.175, 52.177, 52.179, 52.181, 52.301, and 52.303.

APPENDIX A TO PART 52 - DESIGN CERTIFICATION RULE FOR THE U.S. ADVANCED BOILING WATER REACTOR

I. Introduction

Appendix A constitutes the standard design certification for the U.S. Advanced Boiling Water Reactor (ABWR) design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the U.S. ABWR design was GE Nuclear Energy.

II. Definitions

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

E. *Tier 2* means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these

differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by §§ 52.47(a) and 52.47(c), with the exception of generic technical specifications and conceptual design information;

2. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and

3. Combined license (COL) action items (COL license information), which identify certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2* information under Section VIII.B.6.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

- (1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

- (2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2 or 52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Tier 1, Tier 2, and the generic technical specifications in the U.S. ABWR Design Control Document, GE Nuclear Energy, Revision 4 dated March 1997, are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the generic DCD may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. A copy is available for examination and copying at the NRC Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20582 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2, and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information, as set forth in the generic DCD, and the "Technical Support Document for the ABWR" are not part of this appendix. Tier 2 references to the probabilistic risk assessment (PRA) in the ABWR standard safety analysis report do not incorporate the PRA into Tier 2.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the U.S. ABWR design or NUREG-1503, "Final Safety Evaluation Report related to the Certification of the Advanced Boiling Water Reactor Design," (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a combined license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.79, and 52.80, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;
2. Include, as part of its application:
 - a. A plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD for the U.S. ABWR design, as modified and supplemented by the applicant's exemptions and departures;
 - b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;
 - c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;
 - d. Information demonstrating compliance with the site parameters and interface requirements;
 - e. Information that addresses the COL action items; and
 - f. Information required by 10 CFR 52.47 that is not within the scope of this appendix.
3. Include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the U.S. ABWR DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the U.S. ABWR design are in 10 CFR parts 20, 50, 73, and 100, codified as of May 2, 1997, that are applicable and technically relevant, as described in the FSER (NUREG-1503) and Supplement No. 1.

B. The U.S. ABWR design is exempt from portions of the following regulations:

1. Paragraph (f)(2)(iv) of 10 CFR 50.34—Separate Plant Safety Parameter Display Console;
2. Paragraph (f)(2)(viii) of 10 CFR 50.34—Post-Accident Sampling for Boron, Chloride, and Dissolved Gases; and
3. Paragraph (f)(3)(iv) of 10 CFR 50.34—Dedicated Containment Penetration.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the U.S. ABWR design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems,

components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the U.S. ABWR design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(5) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements), and the rulemaking record for certification of the U.S. ABWR design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the U.S. ABWR design;

3. All generic changes to the DCD under and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 pursuant to and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC's final environmental assessment for the U.S. ABWR design and Revision 1 of the technical support document for the U.S. ABWR, dated

December 1994, for plants referencing this appendix whose site parameters are within those specified in the technical support document.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the DCD for the U.S. ABWR design, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from GE Nuclear Energy. The request must state with particularity:

- a. The nature of the proprietary or other information sought;
- b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;

c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If GE Nuclear Energy declines to provide the information sought, GE Nuclear Energy shall send a written response within 10 days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to GE Nuclear Energy), and GE Nuclear Energy's response. The Commission and presiding officer may order GE Nuclear Energy to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from June 11, 1997, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(4).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this

appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 52.7 are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee

who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition the NRC to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

(1) Fuel burnup limit (4.2).

(2) Fuel design evaluation (4.2.3).

(3) Fuel licensing acceptance criteria (appendix 4B).

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2*

matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) ASME Boiler & Pressure Vessel Code, Section III.
- (2) ACI 349 and ANSI/AISC-690.
- (3) Motor-operated valves.
- (4) Equipment seismic qualification methods.
- (5) Piping design acceptance criteria.
- (6) Fuel system and assembly design (4.2), except burnup limit.
- (7) Nuclear design (4.3).
- (8) Equilibrium cycle and control rod patterns (App. 4A).
- (9) Control rod licensing acceptance criteria (App. 4C).
- (10) Instrument setpoint methodology.
- (11) EMS performance specifications and architecture.
- (12) SSLC hardware and software qualification.
- (13) Self-test system design testing features and commitments.
- (14) Human factors engineering design and implementation process.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design

feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic TS and other operational requirements are applicable to all applicants who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved,

as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been met.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been met, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR

52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1. The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.103(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.98 and Section VIII of this appendix.

X. Records and Reporting

A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1, Tier 2, and the generic TS and other operational requirements. The applicant shall maintain the proprietary and safeguards information

referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes and the plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes the finding required by 10 CFR 52.103(g), the report must be submitted

semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 10 CFR 50.71(e)(4), respectively, or at shorter intervals as specified in the license.

APPENDIX B TO PART 52 - DESIGN CERTIFICATION RULE FOR THE SYSTEM 80+ DESIGN

I. Introduction

Appendix B constitutes design certification for the System 80+¹ standard plant design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the System 80+ design was Combustion Engineering, Inc. (ABB-CE), which is now Westinghouse Electric Company LLC.

II. Definitions

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

¹“System 80+” is a trademark of Westinghouse Electric Company LLC.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

E. *Tier 2* means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by §§ 52.47(a) and 52.47(c), with the exception of generic technical specifications and conceptual design information;

2. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and

3. Combined license (COL) action items (COL license information), which identify certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2* information under Section VIII.B.6 of this appendix.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

(1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2 or 52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Tier 1, Tier 2, and the generic technical specifications in the System 80+ Design Control Document, ABB-CE, with revisions dated January 1997, are approved for incorporation

by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the generic DCD may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. A copy is available for examination and copying at the NRC Public Document Room located at One White Flint North 11555 Rockville Pike (first floor) Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20582 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2, and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information, as set forth in the generic DCD, and the Technical Support Document for the System 80+ design are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the System 80+ design or NUREG-1462, "Final Safety Evaluation Report Related to the Certification of the System 80+ Design," (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a combined license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.79, and 52.80, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;
2. Include, as part of its application:
 - a. A plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD for the System 80+ design, as modified and supplemented by the applicant's exemptions and departures;
 - b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;
 - c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;
 - d. Information demonstrating compliance with the site parameters and interface requirements;
 - e. Information that addresses the COL action items; and
 - f. Information required by 10 CFR 52.47 that is not within the scope of this appendix.
3. Include, in the plant-specific DCD, the proprietary information referenced in the System 80+ DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the System 80+ design are in 10 CFR parts 20, 50, 73, and 100, codified as of May 9, 1997, that are applicable and technically relevant, as described in the FSER (NUREG-1462) and Supplement No. 1.

B. The System 80+ design is exempt from portions of the following regulations:

1. Paragraph (f)(2)(iv) of 10 CFR 50.34—Separate Plant Safety Parameter Display Console;
2. Paragraphs (f)(2) (vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34—Accident Source Terms;
3. Paragraph (f)(2)(viii) of 10 CFR 50.34—Post-Accident Sampling for Hydrogen, Boron, Chloride, and Dissolved Gases;
4. Paragraph (f)(3)(iv) of 10 CFR 50.34—Dedicated Containment Penetration; and
5. Paragraphs III.A.1(a) and III.C.3(b) of Appendix J to 10 CFR 50—Containment Leakage Testing.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the System 80+ design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the System 80+ design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(5) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements), and the rulemaking record for certification of the System 80+ design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the System 80+ design;

3. All generic changes to the DCD under and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC's final environmental assessment for the System 80+ design and the technical support document for the System 80+ design, dated January 1995, for plants referencing this appendix whose site parameters are within those specified in the technical support document.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary information or other secondary references in the DCD for the System 80+ design, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse. The request must state with particularity:

- a. The nature of the proprietary or other information sought;
- b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;
- c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within ten (10) days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from June 20, 1997, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(4).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 52.7 are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would - -

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if - -

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition the NRC to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this

appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Maximum fuel rod average burnup.
- (2) Control room human factors engineering.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) ASME Boiler & Pressure Vessel Code, Section III.
- (2) ACI 349 and ANSI/AISC-690.

- (3) Motor-operated valves.
- (4) Equipment seismic qualification methods.
- (5) Piping design acceptance criteria.
- (6) Fuel and control rod design, except burnup limit.
- (7) Instrumentation and controls setpoint methodology.
- (8) Instrumentation and controls hardware and software changes.
- (9) Instrumentation and controls environmental qualification.
- (10) Seismic design criteria for non-seismic Category I structures.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic TS and other operational requirements are applicable to all applicants who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not

completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such a petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been met.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been met, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of Section VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.103(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.98 and Section VIII of this appendix.

X. Records and Reporting

A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1, Tier 2, and the generic TS and other operational requirements. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes the finding required by 10 CFR 52.103(g), the report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), the reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e)(4), respectively, or at shorter intervals as specified in the license.

APPENDIX C TO PART 52 - DESIGN CERTIFICATION RULE FOR THE AP600 DESIGN

I. Introduction

Appendix C constitutes the standard design certification for the AP600¹ design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the AP600 design is Westinghouse Electric Company LLC.

II. Definitions

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);

¹AP600 is a trademark of Westinghouse Electric Company LLC.

4. Significant site parameters; and
5. Significant interface requirements.

E. *Tier 2* means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by §§ 52.47(a) and 52.47(c), with the exception of generic technical specifications and conceptual design information;
2. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
3. Combined license (COL) action items (COL license information), which identify certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.
4. The investment protection short-term availability controls in Section 16.3 of the DCD.

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2* information under Section VIII.B.6.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

(1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2 or 52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3), and the generic technical specifications in the AP600 DCD (12/99 revision) are approved for incorporation by reference by the Director of the Office of the Federal Register on January 24, 2000, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the generic DCD may be obtained from Ronald P. Vijuk, Manager, Passive Plant Engineering, Westinghouse Electric Company, P.O. Box 355, Pittsburgh, Pennsylvania 15230-0355. A copy of the generic DCD is available for examination and copying at the NRC Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2 (including the investment protection short-term availability

controls in Section 16.3), and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information in the generic DCD and the evaluation of severe accident mitigation design alternatives in Appendix 1B of the generic DCD are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the AP600 design or NUREG-1512, "Final Safety Evaluation Report Related to Certification of the AP600 Standard Design," (FSER), then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a combined license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.79, and 52.80, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;

2. Include, as part of its application:

a. A plant-specific DCD containing the same type of information and utilizing the same organization and numbering as the generic DCD for the AP600 design, as modified and supplemented by the applicant's exemptions and departures;

b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;

- c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;
 - d. Information demonstrating compliance with the site parameters and interface requirements;
 - e. Information that addresses the COL action items; and
 - f. Information required by 10 CFR 52.47 that is not within the scope of this appendix.
3. Include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the AP600 DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the AP600 design are in 10 CFR parts 20, 50, 73, and 100, codified as of December 16, 1999, that are applicable and technically relevant, as described in the FSER (NUREG-1512) and the supplementary information for this section.

B. The AP600 design is exempt from portions of the following regulations:

- 1. Paragraph (a)(1) of 10 CFR 50.34—whole body dose criterion;
- 2. Paragraph (f)(2)(iv) of 10 CFR 50.34—Plant Safety Parameter Display Console;
- 3. Paragraphs (f)(2)(vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34—Accident Source Term in TID 14844;
- 4. Paragraph (a)(2) of 10 CFR 50.55a—ASME Boiler and Pressure Vessel Code;
- 5. Paragraph (c)(1) of 10 CFR 50.62—Auxiliary (or emergency) feedwater system;

6. Appendix A to 10 CFR part 50, GDC 17—Offsite Power Sources; and
7. Appendix A to 10 CFR part 50, GDC 19—whole body dose criterion.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the AP600 design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the AP600 design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(5) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements and the investment protection short-term availability controls in Section 16.3), and the rulemaking record for certification of the AP600 design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the AP600 design;

3. All generic changes to the DCD under and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives (SAMDA) associated with the information in the NRC's environmental assessment for the AP600 design and appendix 1B of the generic DCD, for plants referencing this appendix whose site parameters are within those specified in the SAMDA evaluation.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;

2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or

3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the AP600 DCD, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse.

The request must state with particularity:

- a. The nature of the proprietary or other information sought;
- b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;
- c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and
- d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within 10 days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely

on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from January 24, 2000, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(4).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it

finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 52.7 are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or

departure from Tier 1 information, Tier 2* information, or the technical specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment under paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition the NRC to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Maximum fuel rod average burn-up.
- (2) Fuel principal design requirements.
- (3) Fuel criteria evaluation process.
- (4) Fire areas.
- (5) Human factors engineering.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) Nuclear Island structural dimensions.
- (2) ASME Boiler and Pressure Vessel Code, Section III, and Code Case–284.
- (3) Design Summary of Critical Sections.
- (4) ACI 318, ACI 349, and ANSI/AISC—690.
- (5) Definition of critical locations and thicknesses.
- (6) Seismic qualification methods and standards.
- (7) Nuclear design of fuel and reactivity control system, except burn-up limit.
- (8) Motor-operated and power-operated valves.

(9) Instrumentation and control system design processes, methods, and standards.

(10) PRHR natural circulation test (first plant only).

(11) ADS and CMT verification tests (first three plants only).

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic TS and other operational requirements are applicable to all applicants who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant

such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement

activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been met.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been met, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1. The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.103(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2

design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.98 and Section VIII of this appendix.

X. Records and Reporting

A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1, Tier 2, and the generic TS and other operational requirements. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes the finding required by 10 CFR 52.103(g), the report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), the reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e), respectively, or at shorter intervals as specified in the license.

APPENDIX D TO PART 52 - DESIGN CERTIFICATION RULE FOR THE AP1000 DESIGN

1. Introduction

Appendix D constitutes the standard design certification for the AP1000¹ design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the AP1000 design is Westinghouse Electric Company LLC.

II. Definitions

A. *Generic design control document* (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. *Generic technical specifications* means the information required by 10 CFR 50.36 and 50.36a for the portion of the plant that is within the scope of this appendix.

C. *Plant-specific DCD* means the document maintained by an applicant or licensee who references this appendix consisting of the information in the generic DCD as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and

¹AP1000 is a trademark of Westinghouse Electric Company LLC.

5. Significant interface requirements.

E. *Tier 2* means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by §§ 52.47(a) and 52.47(c), with the exception of generic technical specifications and conceptual design information;

2. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and

3. Combined license (COL) action items (COL license information), which identify certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

4. The investment protection short-term availability controls in Section 16.3 of the DCD.

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2* information under paragraph VIII.B.6.

G. *Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:*

1. Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

2. Changing from a method described in the plant-specific DCD to another method unless that method has been approved by the NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2, or 52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3), and the generic TS in the AP1000 DCD (Revision 15, dated December 8, 2005) are approved for incorporation by reference by the Director of the Office of the *Federal Register* on February 27, 2006, under 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the generic DCD may be obtained from Ronald P. Vijuk, Manager, Passive Plant Engineering, Westinghouse Electric Company, P.O. Box 355, Pittsburgh, Pennsylvania 15230-0355. A copy of the generic DCD is also available for examination and copying at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. Copies are available for examination at the NRC Library, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, telephone (301) 415-5610, e-mail LIBRARY@NRC.GOV or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3 of the DCD), and the generic TS except as otherwise provided in this appendix. Conceptual design information in the generic DCD and the evaluation of SAMDAs in appendix 1B of the generic DCD are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the AP1000 design or NUREG-1793, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a combined license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.79, and 52.80, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix.
2. Include, as part of its application:
 - a. A plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD for the AP1000 design, as modified and supplemented by the applicant's exemptions and departures;

- b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;
 - c. Plant-specific TS, consisting of the generic and site-specific TS that are required by 10 CFR 50.36 and 50.36a;
 - d. Information demonstrating compliance with the site parameters and interface requirements;
 - e. Information that addresses the COL action items; and
 - f. Information required by 10 CFR 52.47(a) that is not within the scope of this appendix.
3. Include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the AP1000 DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the AP1000 design are in 10 CFR parts 20, 50, 73, and 100, codified as of January 23, 2006, that are applicable and technically relevant, as described in the FSER (NUREG-1793) and Supplement No. 1.

- B. The AP1000 design is exempt from portions of the following regulations:
- 1. Paragraph (f)(2)(iv) of 10 CFR 50.34 - Plant Safety Parameter Display Console;
 - 2. Paragraph (c)(1) of 10 CFR 50.62 - Auxiliary (or emergency) feedwater system; and
 - 3. Appendix A to 10 CFR part 50, GDC 17 - Second offsite power supply circuit.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the AP1000 design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the AP1000 design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(5) in subsequent proceedings for issuance of a COL, amendment of a COL, or renewal of a COL, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic TS and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information, which the context indicates is intended as requirements, and the investment protection short-term availability controls in Section 16.3 of the DCD), and the rulemaking record for certification of the AP1000 design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the AP1000 design;

3. All generic changes to the DCD under and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning SAMDAs associated with the information in the NRC's EA for the AP1000 design and Appendix 1B of the generic DCD, for plants referencing this appendix whose site parameters are within those specified in the SAMDA evaluation.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except under the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;

2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or

3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the AP1000 DCD, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or

participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse.

The request must state with particularity:

- a. The nature of the proprietary or other information sought;
- b. The reason why the information currently available to the public in the NRC's public document room is insufficient;
- c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and
- d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within 10 days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of this Appendix

This appendix may be referenced for a period of 15 years from February 27, 2006, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(4).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under 10 CFR 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 50.12(a) are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the TS, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Maximum fuel rod average burn-up.
- (2) Fuel principal design requirements.
- (3) Fuel criteria evaluation process.
- (4) Fire areas.
- (5) Human factors engineering.
- (6) Small-break loss-of-coolant accident (LOCA) analysis methodology.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except under paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are subject to the departure provisions in paragraph B.5 of this section.

- (1) Nuclear Island structural dimensions.
- (2) American Society of Mechanical Engineers Boiler & Pressure Vessel Code (ASME Code), Section III, and Code Case–284.
- (3) Design Summary of Critical Sections.
- (4) American Concrete Institute (ACI) 318, ACI 349, American National Standards Institute/American Institute of Steel Construction (ANSI/AISC)–690, and American Iron and Steel Institute (AISI), “Specification for the Design of Cold Formed Steel Structural Members, Part 1 and 2,” 1996 Edition and 2000 Supplement.
- (5) Definition of critical locations and thicknesses.
- (6) Seismic qualification methods and standards.
- (7) Nuclear design of fuel and reactivity control system, except burn-up limit.

- (8) Motor-operated and power-operated valves.
- (9) Instrumentation and control system design processes, methods, and standards.
- (10) Passive residual heat removal (PRHR) natural circulation test (first plant only).
- (11) Automatic depressurization system (ADS) and core make-up tank (CMT)

verification tests (first three plants only).

- (12) Polar crane parked orientation.
- (13) Piping design acceptance criteria.
- (14) Containment vessel design parameters.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic TS and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic TS and other operational requirements are applicable to all applicants who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic TS and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic TS and other operational requirements that were not completely reviewed and approved or require additional

TS and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 52.7. The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license, or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a TS derived from the generic TS must be changed may petition to admit such a contention into the proceeding. The petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or demonstrate compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response to the petition. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific TS or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic TS have no further effect on the plant-specific TS. Changes to the plant-specific TS will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1. An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities. A licensee may also proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been met.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. If an activity is subject to an ITAAC and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been met, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC under Section VIII of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1. The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find that the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.103(a) hearing, their expiration will occur upon final Commission action in such a proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.98 and Section VIII of this appendix.

X. Records and Reporting

A. Records

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1, Tier 2, and the generic TS and other operational requirements. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes its findings required by 10 CFR 52.103(g), the report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), the reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e)(4), respectively, or at shorter intervals as specified in the license.

APPENDICES E THROUGH M TO PART 52 [RESERVED]

**APPENDIX N TO PART 52—STANDARDIZATION OF NUCLEAR POWER PLANT DESIGNS:
COMBINED LICENSES TO CONSTRUCT AND OPERATE NUCLEAR POWER REACTORS
OF IDENTICAL DESIGN AT MULTIPLE SITES**

The Commission’s regulations in part 2 of this chapter specifically provide for the holding of hearings on particular issues separately from other issues involved in hearings in licensing proceedings, and for the consolidation of adjudicatory proceedings and of the presentations of parties in adjudicatory proceedings such as licensing proceedings (§§ 2.316 and 2.317 of this chapter).

This appendix sets out the particular requirements and provisions applicable to situations in which applications for combined licenses under subpart C of this part are filed by one or more applicants for licenses to construct and operate nuclear power reactors of identical design (“common design”) to be located at multiple sites.¹

1. Except as otherwise specified in this appendix or as the context otherwise indicates, the provisions of subpart C of this part and subpart D of part 2 of this chapter apply to combined license applications subject to this appendix.

2. Each combined license application submitted pursuant to this appendix must be submitted as specified in § 52.75 and 10 CFR 2.101. Each application must state that the applicant wishes to have the application considered under 10 CFR part 52, appendix N, and must list each of the applications to be treated together under this appendix.

3. Each application must include the information required by §§ 52.77, 52.79, and 52.80(a) and (b), *provided, however*, that the application must identify the common design, and, if applicable, reference a standard design certification under subpart B of this part, or the use of

¹If the design for the power reactor(s) proposed in a particular application is not identical to the others, that application may not be processed under this appendix and subpart D of part 2 of this chapter.

a reactor manufactured under subpart F of this part. The final safety analysis report for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the final safety analysis report for the referenced design certification or the manufactured reactor.²

4. Each combined license application submitted pursuant to this appendix must contain an environmental report as required by § 52.80(c), and which complies with the applicable provisions of 10 CFR part 51, *provided, however*, that the application may incorporate by reference a single environmental report on the environmental impacts of the common design.

5. Upon a determination that each application is acceptable for docketing under 10 CFR 2.101, each application will be docketed and a notice of docketing for each application will be published in the *Federal Register*, in accordance with 10 CFR 2.104, *provided, however*, that the notice must state that the application will be processed under the provisions of 10 CFR part 52, appendix N, and subpart D of part 2 of this chapter. As the discretion of the Commission, a single notice of docketing for multiple applications may be published in the *Federal Register*.

6. The NRC staff shall prepare draft and final environmental impact statements for each of the applications under part 51 of this chapter. Scoping under 10 CFR 51.28 and 51.29 for each of the combined license applications may be conducted simultaneously, *provided, however*, that joint scoping shall be conducted with respect to the environmental issues relevant to the common design.

If the applications reference a standard design certification, then the environmental impact statement for each of the applications must incorporate by reference the design

²As used in this appendix, the design of a nuclear power reactor included in a single referenced safety analysis report means the design of those structures, systems, and components important to radiological health and safety and the common defense and security.

certification environmental assessment. If the applications do not reference a standard design certification, then the NRC staff shall prepare draft and final supplemental environmental impact statements which address severe accident design mitigation alternatives for the common design, which must be incorporated by reference into the environmental impact statement prepared for each application. Scoping under 10 CFR 51.28 and 51.29 for the supplemental environmental impact statement may be conducted simultaneously, and may be part of the scoping for each of the combined license applications.

7. The ACRS shall report on each of the applications as required by § 52.87. Each report must be limited to those safety matters for each application which are not relevant to the common design. In addition, the ACRS shall separately report on the safety of the common design, *provided, however*, that the report need not address the safety of a referenced standard design certification or reactor manufactured under subpart F of this part.

8. The Commission shall designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters relating to the common design. The hearing will be governed by the applicable provisions of subparts A, C, G, L, N, and O of part 2 of this chapter relating to applications for combined licenses. The presiding officer shall issue a partial initial decision on the common design.

APPENDIX O TO PART 52 [RESERVED]

APPENDIX P TO PART 52 [RESERVED]

**APPENDIX Q TO PART 52--PRE-APPLICATION EARLY REVIEW OF SITE SUITABILITY
ISSUES**

This appendix sets out procedures for the filing, staff review, and referral to the Advisory Committee on Reactor Safeguards (ACRS) of requests for early review of one or more site suitability issues relating to the construction and operation of certain utilization facilities separately from and prior to the submittal of applications for early site permits or combined licenses for the facilities. The appendix also sets out procedures for the preparation and issuance of staff site reports and for their incorporation by reference in applications for early site permits or combined licenses for the construction and operation of certain utilization facilities. The utilization facilities are those which are subject to § 51.20(b) of this chapter and are of the type specified in § 50.22 of this chapter. This appendix does not apply to proceedings conducted pursuant to subpart F or part 2 of this chapter.

1. Any person may submit information regarding one or more site suitability issues to the Commission's staff for its review separately from and prior to an application for an early site permit or a combined license for a facility. Such a submittal shall be accompanied by any fee required by part 170 of this chapter and shall consist of the portion of the information required of applicants by §§ 50.33 (a) through (c) and (e) of this chapter, and, insofar as it relates to the issue(s) of site suitability for which early review is sought, by § 52.17 or by §§ 52.79(a) and 52.80(c) of this part, except that information with respect to operation of the facility at the projected initial power level need not be supplied.

2. The submittal for early review of site suitability issue(s) must be made in the same manner as provided in §§ 52.3 and 52.15 of this part for early site permit applications or as provided in §§ 52.3 and 52.75 of this part for combined license applications. The submittal must include sufficient information concerning range of postulated facility design and operation parameters to enable the staff to perform the requested review of site suitability issues. The submittal must contain suggested conclusions on the issues of site suitability submitted for review and must be accompanied by a statement of the bases or the reasons for those

conclusions. The submittal must also list, to the extent possible, any long-range objectives for ultimate development of the site, state whether any site selection process was used in preparing the submittal, describe any site selection process used, and explain what consideration, if any, was given to alternative sites.

3. The staff shall publish a note of docketing of the submittal in the *Federal Register*, and shall send a copy of the notice of docketing to the Governor or other appropriate official of the State in which the site is located. This notice shall identify the location of the site, briefly describe the site suitability issue(s) under review, and invite comments from Federal, State, and local agencies and interested persons within 120 days of publication or such other time as may be specified, for consideration by the staff in connection with the initiation or outcome of the review and, if appropriate by the ACRS, in connection with the outcome of their review. The person requesting review shall serve a copy of the submittal on the Governor or other appropriate official of the State in which the site is located, and on the chief executive of the municipality in which the site is located or, if the site is not located in a municipality, on the chief executive of the county. The portion of the submittal containing information requested of applicants for early site permits by § 50.33 (a) through (c) and (e) of this chapter and § 52.17 of this part, or of applicants for combined licenses by § 50.33 (a) through (c) and (e) of this chapter and § 52.79(a) of this part, will be referred to the ACRS for a review and report. There will be no referral to the ACRS unless early review of the site safety issues under § 52.17 or § 52.79(a) is requested.

4. Upon completion of review by the NRC staff and, if appropriate by the ACRS, of a submittal under this appendix, the NRC staff shall prepare a staff site report which shall identify the location of the site, state the site suitability issues reviewed, explain the nature and scope of the review, state the conclusions of the staff regarding the issues reviewed and state the reasons for those conclusions. Upon issuance of an NRC staff site report, the NRC staff shall

publish a notice of the availability of the report in the *Federal Register* and shall make available a copy of the report at the NRC Web site, <http://www.nrc.gov>. The NRC staff shall also send a copy of the report to the Governor or other appropriate official of the State in which the site is located, and to the chief executive of the municipality in which the site is located or, if the site is not located in a municipality, to the chief executive of the county.

5. Any staff site report prepared and issued in accordance with this appendix may be incorporated by reference, as appropriate, in an application for an early site permit or a combined license for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specific in § 50.22 of this chapter. The conclusions of the staff site report will be re-examined by the staff where 5 years or more have elapsed between the issuance of the staff site report and its incorporation by reference in an early site permit or a combined license application.

6. Issuance of a staff site report shall not constitute a commitment to issue a permit or license, to permit onsite work under § 50.10(e) of this chapter, or in any way affect the authority of the Commission, Atomic Safety and Licensing Appeal Panel, Atomic Safety and Licensing Board Panel, and other presiding officers in any proceeding under part 2 of this chapter.

7. The staff will not conduct more than one review of site suitability issues with regard to a particular site prior to the full combined license review required by subpart A of part 51 of this chapter. The staff may decline to prepare and issue a staff site report in response to a submittal under this appendix where it appears that: (a) in cases where no review of the relative merits of the submitted site and alternative sites under subpart A of part 51 of this chapter is requested, there is a reasonable likelihood that further staff review would identify one or more preferable alternative sites and the staff review of one or more site suitability issues would lead to an irreversible and irretrievable commitment of resources prior to the submittal of the analysis of alternative sites in the environmental report that would prejudice the later review

and decision on alternative sites under part 2 and subpart A of part 51 of this chapter; or (b) in cases where, in the judgment of the staff, early review of any site suitability issue or issues would not be in the public interest, considering

(a) the degree of likelihood that any early findings on those issues would retain their validity in later reviews,

(b) the objections, if any, of cognizant state or local government agencies to the conduct of an early review on those issues, and

(c) the possible effect on the public interest of having an early, if not necessarily conclusive, resolution of those issues.

PART 54 - REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR POWER PLANTS

153. The authority citation for Part 54 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 161, 181, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs 201, 202, 206, 88 Stat. 1242, 1244, as amended (42 U.S.C. 5841, 5842).

Section 54.17 also issued under E.O.12829, 3 CFR, 1993 Comp., p. 570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p. 333; E.O. 12968, 3 CFR, 1995 Comp., p. 391.

154. Section 54.1 is revised to read as follows:

§ 54.1 Purpose.

This part governs the issuance of renewed operating licenses and renewed combined licenses for nuclear power plants licensed pursuant to Sections 103 or 104b of the Atomic

Energy Act of 1954, as amended, and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242).

155. In § 54.3, paragraph (a), the definition for *Current licensing basis* is revised, and the definition for *Renewed combined license* is added to read as follows:

§ 54.3 Definitions.

(a)* * *

Current licensing basis (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

* * * * *

Renewed combined license means a combined license originally issued under part 52 of this chapter for which an application for renewal is filed in accordance with 10 CFR 52.107 and issued under this part.

* * * * *

156. In § 54.17, paragraph (c) is revised to read as follows:

§ 54.17 Filing of application.

* * * * *

(c) An application for a renewed license may not be submitted to the Commission earlier than 20 years before the expiration of the operating license or combined license currently in effect.

* * * * *

157. Section 54.27 is revised to read as follows:

§ 54.27 Hearings.

A notice of an opportunity for a hearing will be published in the *Federal Register* in accordance with 10 CFR 2.105. In the absence of a request for a hearing filed within 30 days by a person whose interest may be affected, the Commission may issue a renewed operating license or renewed combined license without a hearing upon 30-day notice and publication in the *Federal Register* of its intent to do so.

158. In Section 54.31, paragraphs (a), (b), and (c) are revised to read as follows:

§ 54.31 Issuance of a renewed license.

(a) A renewed license will be of the class for which the operating license or combined license currently in effect was issued.

(b) A renewed license will be issued for a fixed period of time, which is the sum of the additional amount of time beyond the expiration of the operating license or combined license (not to exceed 20 years) that is requested in a renewal application plus the remaining number

of years on the operating license or combined license currently in effect. The term of any renewed license may not exceed 40 years.

(c) A renewed license will become effective immediately upon its issuance, thereby superseding the operating license or combined license previously in effect. If a renewed license is subsequently set aside upon further administrative or judicial appeal, the operating license or combined license previously in effect will be reinstated unless its term has expired and the renewal application was not filed in a timely manner.

* * * * *

159. Section 54.35 is revised to read as follows:

§ 54.35 Requirements during term of renewed license.

During the term of a renewed license, licensees shall be subject to and shall continue to comply with all Commission regulations contained in 10 CFR parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, and 100, and the appendices to these parts that are applicable to holders of operating licenses or combined licenses, respectively.

160. In § 54.37, paragraph (a) is revised to read as follows:

§ 54.37 Additional records and recordkeeping requirements.

(a) The licensee shall retain in an auditable and retrievable form for the term of the renewed operating license or renewed combined license all information and documentation required by, or otherwise necessary to document compliance with, the provisions of this part.

* * * * *

PART 55 - OPERATORS' LICENSES

161. The authority citation for Part 55 continues to read as follows:

AUTHORITY: Secs. 107, 161, 182, 68 Stat. 939, 948, 953 , as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2137, 2201, 2232, 2282); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Sections 55.41, 55.43, 55.45, and 55.59 also issued under sec. 306, Pub. L. 97-425, 96 Stat. 2262 (42 U.S.C. 10226). Section 55.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237).

162. In § 55.1, paragraph (a) is revised to read as follows:

§ 55.1 Purpose.

* * * * *

(a) Establish procedures and criteria for the issuance of licenses to operators and senior operators of utilization facilities licensed under the Atomic Energy Act of 1954, as amended, or Section 202 of the Energy Reorganization Act of 1974, as amended, and part 50, part 52, or part 54 of this chapter,

* * * * *

163. In § 55.2, paragraph (a) is revised to read as follows:

§ 55.2 Scope.

* * * * *

(a) Any individual who manipulates the controls of any utilization facility licensed under parts 50, 52, or 54 of this chapter,

* * * * *

164. In § 55.5, paragraph (b)(1) and the introductory text of paragraph (b)(2) are revised to read as follows:

§ 55.5 Communications.

* * * * *

(b)(1) Except for test and research reactor facilities, the Director of Nuclear Reactor Regulation has delegated to the Regional Administrators of Regions I, II, III, and IV authority and responsibility under the regulations in this part for the issuance and renewal of licenses for operators and senior operators of nuclear power reactors licensed under 10 CFR part 50 or part 52 and located in these regions.

(2) Any application for a license or license renewal filed under the regulations in this part involving a nuclear power reactor licensed under 10 CFR part 50 or part 52 and any related inquiry, communication, information, or report must be submitted to the Regional Administrator by an appropriate method listed in paragraph (a) of this section. The Regional Administrator or the Administrator's designee will transmit to the Director of New Reactors or the Director of Nuclear Reactor Regulation, as appropriate, any matter that is not within the scope of the Regional Administrator's delegated authority.

* * * * *

**PART 72 - LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT
NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE AND REACTOR RELATED
GREATER THAN CLASS C WASTE**

165. The authority citation for Part 72 continues to read as follows:

AUTHORITY: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444,

as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

166. Section 72.210 is revised to read as follows:

§ 72.210 General license issued.

A general license is hereby issued for the storage of spent fuel in an independent spent fuel storage installation at power reactor sites to persons authorized to possess or operate nuclear power reactors under 10 CFR part 50 or 10 CFR part 52.

167. In § 72.218, paragraph (b) is revised to read as follows:

§ 72.218 Termination of licenses.

* * * * *

(b) An application for termination of a reactor operating license issued under 10 CFR part 50 and submitted under § 50.82 of this chapter, or a combined license issued under 10 CFR part 52 and submitted under § 52.110 of this chapter, must contain a description of how the spent fuel stored under this general license will be removed from the reactor site.

* * * * *

PART 73 - PHYSICAL PROTECTION OF PLANTS AND MATERIALS

168. The authority citation for Part 73 continues to read as follows:

AUTHORITY: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99-399, 100 Stat. 876 (42 U.S.C. 2169).

169. In § 73.1, paragraph (b)(1)(i) is revised to read as follows:

§ 73.1 Purpose and scope.

* * * * *

(b)* * *

(1)* * *

(i) The physical protection of production and utilization facilities licensed under parts 50 or 52 of this chapter,

* * * * *

170. In § 73.2, the introductory text of paragraph (a) is revised to read as follows:

§ 73.2 Definitions.

* * * * *

(a) Terms defined in parts 50, 52, and 70 of this chapter have the same meaning when used in this part.

* * * * *

171. In § 73.50, the introductory text is revised to read as follows:

§ 73.50 Requirements for physical protection of licensed activities.

Each licensee who is not subject to § 73.51, but who possesses, uses, or stores formula quantities of strategic special nuclear material that are not readily separable from other radioactive material and which have total external radiation dose rates in excess of 100 rems per hour at a distance of 3 feet from any accessible surfaces without intervening shielding other than at nuclear reactor facility licensed under parts 50 or 52 of this chapter, shall comply with the following:

* * * * *

172. In § 73.56, paragraph (a)(3) is revised to read as follows:

§ 73.56 Personnel access authorization requirements for nuclear power plants.

(a)* * *

(3) Each applicant for a license to operate a nuclear power reactor under §§ 50.21(b) or 50.22 of this chapter, including an applicant for a combined license under part 52 of this

chapter, whose application is submitted after April 25, 1991, shall include the required access authorization program as part of its Physical Security Plan. The applicant, upon receipt of an operating license or upon notice of the Commission's finding under § 52.103(g) of this chapter, shall implement the required access authorization program as part of its site Physical Security Plan.

* * * * *

173. In § 73.57, paragraphs (a)(1), (a)(2), and (a)(3) are revised to read as follows:

§ 73.57 Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information by power reactor licensees.

(a)* * *

(1) Each licensee who is authorized to operate a nuclear power reactor under part 50 of this chapter, or each holder of a combined license under part 52 of this chapter upon receipt of notice of the Commission's finding under § 52.103(g), shall comply with the requirements of this section.

(2) Each applicant for a license to operate a nuclear power reactor under part 50 of this chapter and each applicant for a combined license under part 52 of this chapter shall submit fingerprints for those individuals who have or will have access to Safeguards Information.

(3) Before receiving its operating license under part 50 of this chapter or before the Commission makes its finding under § 52.103(g) of this chapter, each applicant for a license to operate a nuclear power reactor (including an applicant for a combined license) may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility.

174. In Appendix C to Part 73, the Introduction is revised to read as follows:

APPENDIX C TO PART 73--LICENSEE SAFEGUARDS CONTINGENCY PLANS

Introduction

A licensee safeguards contingency plan is a documented plan to give guidance to licensee personnel in order to accomplish specific defined objectives in the event of threats, thefts, or radiological sabotage relating to special nuclear material or nuclear facilities licensed under the Atomic Energy Act of 1954, as amended. An acceptable safeguards contingency plan must contain:

- (1) A predetermined set of decisions and actions to satisfy stated objectives;
- (2) An identification of the data, criteria, procedures, and mechanisms necessary to efficiently implement the decisions; and
- (3) A stipulation of the individual, group, or organizational entity responsible for each decision and action.

The goals of licensee safeguards contingency plans for responding to threats, thefts, and radiological sabotage are:

- (1) To organize the response effort at the licensee level;
- (2) To provide predetermined, structured responses by licensees to safeguards contingencies;
- (3) To ensure the integration of the licensee response with the responses by other entities; and
- (4) To achieve a measurable performance in response capability.

Licensee safeguards contingency planning should result in organizing the licensee's resources in such a way that the participants will be identified, their several responsibilities specified, and the responses coordinated. The responses should be timely.

It is important to note that a licensee's safeguards contingency plan is intended to be complementary to any emergency plans developed under appendix E to part 50 of this chapter, § 52.17 or § 52.79, or to § 70.22(i) of this chapter.

* * * * *

**PART 75 - SAFEGUARDS ON NUCLEAR MATERIAL - IMPLEMENTATION OF US/IAEA
AGREEMENT**

175. The authority citation for Part 75 continues to read as follows

AUTHORITY: Secs. 53, 63, 103, 104, 122, 161, 68 Stat. 930, 932, 936, 937, 939, 948, as amended (42 U.S.C. 2073, 2093, 2133, 2134, 2152, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 75.4 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

176. In § 75.6, paragraph (b) is revised to read as follows:

§ 75.6 Maintenance of records and delivery of information, reports, and other communications.

* * * * *

(b) If an installation is a nuclear power plant or a non-power reactor for which a construction permit, operating license or a combined license has been issued, whether or not a license to receive and possess nuclear material at the installation has been issued, the

cognizant Director is either the Director, Office of New Reactors, or the Director, Office of Nuclear Reactor Regulation. For all other installations, the cognizant Director is the Director, Office of Nuclear Material Safety and Safeguards.

* * * * *

PART 95 - FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

177. The authority citation for Part 95 continues to read as follows:

AUTHORITY: Secs. 145, 161, 193, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); E.O. 10865, as amended, 3 CFR 1959-1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12829, 3 CFR, 1993 Comp., p. 570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p. 333, as amended by E.O. 13292, 3 CFR, 2004 Comp., p. 196; E.O. 12968, 3 CFR, 1995 Comp., p. 391.

178. In § 95.5, the definition of *license* is revised to read as follows:

§ 95.5 Definitions.

* * * * *

License means a license issued under 10 CFR parts 50, 52, 54, 60, 63, 70, or 72.

* * * * *

179. In § 95.13, paragraph (b) is revised to read as follows:

§ 95.13 Maintenance of records.

* * * * *

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee, certificate holder, or other person shall maintain adequate safeguards against tampering with and loss of records.

180. In § 95.19, the introductory text of paragraph (b) is revised to read as follows:

§ 95.19 Changes to security practices and procedures.

* * * * *

(b) A licensee, certificate holder, or other person may effect a minor, non-substantive change to an approved Standard Practice Procedures Plan for the safeguarding of classified information without receiving prior CSA approval. These minor changes that do not affect the security of the facility may be submitted to the addressees noted in paragraph (a) of this section within 30 days of the change. Page changes rather than a complete rewrite of the plan may be submitted. Some examples of minor, non-substantive changes to the Standard Practice Procedures Plan include—

* * * * *

181. Section 95.20 is revised to read as follows:

§ 95.20 Grant, denial or termination of facility clearance.

The Division of Nuclear Security shall provide notification in writing (or orally with written confirmation) to the licensee, certificate holder, or other person of the Commission's grant, acceptance of another agency's facility clearance, denial, or termination of facility clearance. This information must also be furnished to representatives of the NRC, NRC contractors, licensees, certificate holders, or other person, or other Federal agencies having a need to transmit classified information to the licensees or other person.

182. In § 95.23, paragraph (b) is revised to read as follows:

§ 95.23 Termination of facility clearance.

* * * * *

(b) When facility clearance is terminated, the licensee, certificate holder, or other person will be notified in writing of the determination and the procedures outlined in § 95.53 apply.

183. Section 95.31 is revised to read as follows:

§ 95.31 Protective personnel.

Whenever protective personnel are used to protect classified information they shall:

(a) Possess an "L" access authorization (or CSA equivalent) if the licensee, certificate holder, or other person possesses information classified Confidential National Security Information, Confidential Restricted Data or Secret National Security Information.

(b) Possess a "Q" access authorization (or CSA equivalent) if the licensee, certificate holder, or other person possesses Secret Restricted Data related to nuclear weapons design, manufacturing and vulnerability information; and certain particularly sensitive Naval Nuclear Propulsion Program information (e.g., fuel manufacturing technology) and the protective personnel require access as part of their regular duties.

184. In § 95.33, paragraph (c) is revised to read as follows:

§ 95.33 Security education.

* * * * *

(c) Temporary Help Suppliers. A temporary help supplier, or other contractor who employs cleared individuals solely for dispatch elsewhere, is responsible for ensuring that required briefings are provided to their cleared personnel. The temporary help supplier or the using licensee's, certificate holder's, or other person's facility may conduct these briefings.

* * * * *

185. Section 95.34 is revised to read as follows:

§ 95.34 Control of visitors.

(a) Uncleared visitors. Licensees, certificate holders, or other persons subject to this part shall take measures to preclude access to classified information by uncleared visitors.

(b) Foreign visitors. Licensees, certificate holders, or other persons subject to this part shall take measures as may be necessary to preclude access to classified information by foreign visitors. The licensee, certificate holder, or other person shall retain records of visits for 5 years beyond the date of the visit.

186. In § 95.35, the introductory text of paragraph (a), and paragraph (a)(3) are revised to read as follows:

§ 95.35 Access to matters classified as National Security Information and Restricted Data.

(a) Except as the Commission may authorize, no licensee, certificate holder or other person subject to the regulations in this part may receive or may permit any other licensee,

certificate holder, or other person to have access to matter revealing Secret or Confidential National Security Information or Restricted Data unless the individual has:

* * * * *

(3) NRC-approved storage facilities if classified documents or material are to be transmitted to the licensee, certificate holder, or other person.

* * * * *

187. In § 95.36, paragraphs (c), (d) and (e) are revised to read as follows:

§ 95.36 Access by representatives of the International Atomic Energy Agency or by participants in other international agreements.

* * * * *

(c) In accordance with the specific disclosure authorization provided by the Division of Nuclear Security, licensees, certificate holders, or other persons subject to this part are authorized to release (*i.e.*, transfer possession of) copies of documents that contain classified National Security Information directly to IAEA inspectors and other representatives officially designated to request and receive classified National Security Information documents. These documents must be marked specifically for release to IAEA or other international organizations in accordance with instructions contained in the NRC's disclosure authorization letter. Licensees, certificate holders, and other persons subject to this part may also forward these documents through the NRC to the international organization's headquarters in accordance with the NRC disclosure authorization. Licensees, certificate holders, and other persons may not reproduce documents containing classified National Security Information except as provided in § 95.43.

(d) Records regarding these visits and inspections must be maintained for 5 years beyond the date of the visit or inspection. These records must specifically identify each

document released to an authorized representative and indicate the date of the release. These records must also identify (in such detail as the Division of Nuclear Security, by letter, may require) the categories of documents that the authorized representative has had access and the date of this access. A licensee, certificate holder, or other person subject to this part shall also retain Division of Nuclear Security disclosure authorizations for 5 years beyond the date of any visit or inspection when access to classified information was permitted.

(e) Licensees, certificate holders, or other persons subject to this part shall take such measures as may be necessary to preclude access to classified matter by participants of other international agreements unless specifically provided for under the terms of a specific agreement.

188. In § 95.37, paragraphs (a), (b) and (h) are revised to read as follows:

§ 95.37 Classification and preparation of documents.

(a) *Classification.* Classified information generated or possessed by a licensee, certificate holder, or other person must be appropriately marked. Classified material which is not conducive to markings (e.g., equipment) may be exempt from this requirement. These exemptions are subject to the approval of the CSA on a case-by-case basis. If a person or facility generates or possesses information that is believed to be classified based on guidance provided by the NRC or by derivation from classified documents, but which no authorized classifier has determined to be classified, the information must be protected and marked with the appropriate classification markings pending review and signature of an NRC authorized classifier. This information shall be protected as classified information pending final determination.

(b) *Classification consistent with content.* Each document containing classified information shall be classified Secret or Confidential according to its content. NRC licensees,

certificate holders, or other persons subject to the requirements of 10 CFR part 95 may not make original classification decisions.

* * * * *

(h) *Classification challenges.* Licensees, certificate holders, or other persons in authorized possession of classified National Security Information who in good faith believe that the information's classification status (*i.e.*, that the document), is classified at either too high a level for its content (overclassification) or too low for its content (underclassification) are expected to challenge its classification status. Licensees, certificate holders, or other persons who wish to challenge a classification status shall—

(1) Refer the document or information to the originator or to an authorized NRC classifier for review. The authorized classifier shall review the document and render a written classification decision to the holder of the information.

(2) In the event of a question regarding classification review, the holder of the information or the authorized classifier shall consult the NRC Division of Facilities and Security, Information Security Branch, for assistance.

(3) Licensees, certificate holders, or other persons who challenge classification decisions have the right to appeal the classification decision to the Interagency Security Classification Appeals Panel.

(4) Licensees, certificate holders, or other persons seeking to challenge the classification of information will not be the subject of retribution.

* * * * *

189. In § 95.39, paragraph (a) is revised to read as follows:

§ 95.39 External transmission of documents and material.

(a) Restrictions. Documents and material containing classified information received or originated in connection with an NRC license, certificate, or standard design approval or standard design certification under part 52 of this chapter must be transmitted only to CSA approved security facilities.

* * * * *

190. In § 95.43, paragraph (a) is revised to read as follows:

§ 95.43 Authority to reproduce.

(a) Each licensee, certificate holder, or other person possessing classified information shall establish a reproduction control system to ensure that reproduction of classified material is held to the minimum consistent with operational requirements. Classified reproduction must be accomplished by authorized employees knowledgeable of the procedures for classified reproduction. The use of technology that prevents, discourages, or detects the unauthorized reproduction of classified documents is encouraged.

* * * * *

191. In § 95.45, paragraph (d) is revised to read as follows:

§ 95.45 Changes in classification.

* * * * *

(d) Any licensee, certificate holder, or other person making a change in classification or receiving notice of such a change shall forward notice of the change in classification to holders of all copies as shown on their records.

192. Section 95.49 is revised to read as follows:

§ 95.49 Security of automatic data processing (ADP) systems.

Classified data or information may not be processed or produced on an ADP system unless the system and procedures to protect the classified data or information have been approved by the CSA. Approval of the ADP system and procedures is based on a satisfactory ADP security proposal submitted as part of the licensee's, certificate holder's, or other person's request for facility clearance outlined in § 95.15 or submitted as an amendment to its existing Standard Practice Procedures Plan for the protection of classified information.

193. Section 95.51 is revised to read as follows:

§ 95.51 Retrieval of classified matter following suspension or revocation of access authorization.

In any case where the access authorization of an individual is suspended or revoked in accordance with the procedures set forth in part 25 of this chapter, or other relevant CSA procedures, the licensee, certificate holder, or other person shall, upon due notice from the Commission of such suspension or revocation, retrieve all classified information possessed by the individual and take the action necessary to preclude that individual having further access to the information.

194. Section 95.53 is revised to read as follows:

§ 95.53 Termination of facility clearance.

(a) If the need to use, process, store, reproduce, transmit, transport, or handle classified matter no longer exists, the facility clearance will be terminated. The licensee, certificate holder, or other person for the facility may deliver all documents and matter containing classified information to the Commission, or to a person authorized to receive them,

or must destroy all classified documents and matter. In either case, the licensee, certificate holder, or other person for the facility shall submit a certification of nonpossession of classified information to the NRC Division of Nuclear Security within 30 days of the termination of the facility clearance.

(b) In any instance where a facility clearance has been terminated based on a determination of the CSA that further possession of classified matter by the facility would not be in the interest of the national security, the licensee, certificate holder, or other person for the facility shall, upon notice from the CSA, dispose of classified documents in a manner specified by the CSA.

195. In § 95.57, the introductory paragraph is revised to read as follows:

§ 95.57 Reports.

Each licensee, certificate holder, or other person having a facility clearance shall report to the CSA and the Regional Administrator of the appropriate NRC Regional Office listed in 10 CFR part 73, appendix A:

* * * * *

196. Section 95.59 is revised to read as follows:

§ 95.59 Inspections.

The Commission shall make inspections and reviews of the premises, activities, records and procedures of any licensee, certificate holder, or other person subject to the regulations in this part as the Commission and CSA deem necessary to effect the purposes of the Act, E.O. 12958 and/or NRC rules.

PART 140 - FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY AGREEMENTS

197. The authority citation for Part 140 continues to read as follows:

AUTHORITY: Secs. 161, 170, 68 Stat. 948, 71 Stat. 576, as amended (42 U.S.C. 2201, 2210); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 841, 5842); Sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

198. In § 140.2, paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 140.2 Scope.

(a)* * *

(1) To each person who is an applicant for or holder of a license issued under 10 CFR parts 50, 52 or 54 to operate a nuclear reactor, and

(2) With respect to an extraordinary nuclear occurrence, to each person who is an applicant for or holder of a license to operate a production facility or a utilization facility (including an operating license issued under part 50 of this chapter and a combined license under part 52 of this chapter), and to other persons indemnified with respect to the involved facilities.

* * * * *

199. Section 140.10 is revised to read as follows:

§ 140.10 Scope.

This subpart applies to each person who is an applicant for or holder of a license issued under 10 CFR parts 50 or 54 to operate a nuclear reactor, or is the applicant for or holder of a combined license issued under parts 52 or 54 of this chapter, except licenses held by persons found by the Commission to be Federal agencies or nonprofit educational institutions licensed

to conduct educational activities. This subpart also applies to persons licensed to possess and use plutonium in a plutonium processing and fuel fabrication plant.

200. In § 140.11, paragraph (b) is revised to read as follows:

§ 140.11 Amounts of financial protection for certain reactors.

* * * * *

(b) In any case where a person is authorized under parts 50, 52 or 54 of this chapter to operate two or more nuclear reactors at the same location, the total primary financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such primary financial protection covers all reactors at the location.

201. In § 140.12, paragraph (c) is revised to read as follows:

§ 140.12 Amount of financial protection required for other reactors.

* * * * *

(c) In any case where a person is authorized under parts 50, 52 or 54 of this chapter to operate two or more nuclear reactors at the same location, the total financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such financial protection covers all reactors at the location.

* * * * *

202. Section 140.13 is revised to read as follows:

§ 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under 10 CFR part 52.

Each holder of a part 50 construction permit, or a holder of a combined license under part 52 of this chapter before the date that the Commission had made the finding under 10 CFR 52.103(g), who also holds a license under part 70 of this chapter authorizing ownership, possession and storage only of special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of either an operating license under 10 CFR part 50 or combined license under 10 CFR part 52, shall, during the period before issuance of a license authorizing operation under parts 50, or the period before the Commission makes the finding under § 52.103(g) of this chapter, as applicable, have and maintain financial protection in the amount of \$1,000,000. Proof of financial protection shall be filed with the Commission in the manner specified in § 140.15 of this chapter before issuance of the license under part 70 of this chapter.

203. In § 140.20, paragraph (a)(1)(ii) is revised, and paragraph (a)(1)(iii) is added to read as follows:

§ 140.20 Indemnity agreements and liens.

(a)* * *

(1)* * *

(ii) The date that the Commission makes the finding under § 52.103(g) of this chapter;

or

(iii) The effective date of the license (issued under part 70 of this chapter) authorizing the licensee to possess and store special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of an operating license for the

reactor, whichever is earlier. No such agreement, however, shall be effective prior to September 26, 1957; or

* * * * *

204. In § 140.81, paragraph (a) is revised to read as follows:

§ 140.81 Scope and purpose.

(a) *Scope.* This subpart applies to applicants for and holders of licenses authorizing operation of production facilities and utilization facilities, including combined licenses under part 52 of this chapter, and to other persons indemnified with respect to such facilities.

* * * * *

205. In § 140.93 Appendix C, Article VIII, paragraph 4 is revised to read as follows:

§ 140.93 Appendix C - Form of indemnity agreement with licensees furnishing proof of financial protection in the form of licensee's resources.

* * * * *

ARTICLE VIII

* * * * *

4. If the Commission determines that the licensee is financially able to reimburse the Commission for a deferred premium payment made in its behalf, and the licensee, after notice of such determination by the Commission fails to make such reimbursement within 120 days, the Commission will take appropriate steps to suspend the license for 30 days. The Commission may take any further action as necessary if reimbursement is not made within the 30-day suspension period including, but not limited to, termination of the operating license or combined license.

* * * * *

206. Section 140.96 is revised to read as follows:

§ 140.96 Appendix F – Indemnity locations.

(a) *Geographical boundaries of indemnity locations.*

(1) In every indemnity agreement between the Commission and a licensee which affords indemnity protection for the preoperational storage of fuel at the site of a nuclear power reactor under construction, the geographical boundaries of the indemnity location will include the entire construction area of the nuclear power reactor, as determined by the Commission. Such area will not necessarily be coextensive with the indemnity location which will be established at the time an operating license or combined license under 10 CFR part 52 is issued for such additional nuclear power reactors.

(2) In every indemnity agreement between the Commission and a licensee which affords indemnity protection for an existing nuclear power reactor, the geographical boundaries of the indemnity location shall include the entire construction area of any additional nuclear power reactor as determined by the Commission, built as part of the same power station by the same licensee. Such area will not necessarily be coextensive with the indemnity location which will be established at the time an operating license or combined license is issued for such additional nuclear power reactors.

(3) This section is effective May 1, 1973, as to construction permits issued before March 2, 1973, and, as to construction permits and combined licenses issued on or after March 2, 1973, the provisions of this section will apply no later than such time as a construction permit or combined license is issued authorizing construction of any additional nuclear power reactor.

**PART 170 - FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND
OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS
AMENDED**

207. The authority citation for Part 170 continues to read as follows:

AUTHORITY: Sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, pub. L. 101-576, 104 Stat. 2842, as amended (31 U.S.C. 901, 902); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

208. In § 170.2, paragraph (j) is removed and reserved, and paragraphs (g) and (k) are revised to read as follows:

§ 170.2 Scope.

* * * * *

(g) An applicant for or holder of a production or utilization facility construction permit or operating license issued under 10 CFR part 50, or an early site permit, standard design certification, standard design approval, manufacturing license, or combined license issued under 10 CFR part 52;

* * * * *

(j) **[Reserved]**

(k) Applying for or already has applied for review, under appendix Q to 10 CFR part 50 or 10 CFR part 52 of a facility site before the submission of an application for a construction permit, early site permit, or combined license;

* * * * *

PART 171 - ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIAL LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY NRC

209. The authority citation for Part 171 continues to read as follows:

AUTHORITY: Sec. 7601, Pub. L. 99-272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100-203, 101 Stat. 1330 as amended by sec. 3201, Pub. L. 101-239, 103 Stat. 2132, as amended by sec. 6101, Pub. L. 101-508, 104 Stat. 1388, as amended by sec. 2903a, Pub. L. 102-486, 106 Stat. 3125 (42 U.S.C. 2213, 2214); sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

210. In § 171.15, paragraph (a) is revised to read as follows:

§ 171.15 Annual Fees: Reactor licenses and independent spent fuel storage licenses.

(a) Each person holding an operating license for a power, test, or research reactor; each person holding a combined license under part 52 of this chapter after the Commission has made the finding under § 52.103(g); each person holding a part 50 or part 52 power reactor license that is in decommissioning or possession only status, except those that have no spent fuel onsite; and each person holding a part 72 license who does not hold a part 50 or part 52

license shall pay the annual fee for each license held at any time during the Federal fiscal year in which the fee is due. This paragraph does not apply to test and research reactors exempted under § 171.11(a).

* * * * *

Dated at Rockville, Maryland, this day of

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

Attachment

Table 1. Cross-References Between Final 10 CFR Part 52 and Existing Requirements

<u>Final Rule</u>	<u>Existing Requirements</u>
<i>General Provisions</i>	
52.0	52.1
52.1	52.3
52.2	52.5
52.3	None
52.4	52.9
52.5	None
52.6	None
52.7	None
52.8	None
52.9	None
52.10	None
52.11	52.8
<i>Subpart A – Early Site Permits</i>	
52.12	52.11
52.13	52.13
52.15	52.15
52.16	None
52.17	52.17
52.18	52.18
None	52.19
52.21	52.21
52.23	52.23
52.24	52.24
52.25	52.25
52.27	52.27
52.28	None
52.29	52.29
52.31	52.31
52.33	52.33
52.35	52.35
None	52.37
52.39	52.39
<i>Subpart B – Standard Design Certifications</i>	
52.41	52.41 and 52.45
52.43	52.43
52.45	52.45 and 52.49
52.46	None
52.47	52.47
52.48	52.48
52.51	52.51
52.53	52.53
52.54	52.54

52.55	52.55
52.57	52.57
52.59	52.59
52.61	52.61
52.63	52.63
<i>Subpart C – Combined Licenses</i>	
52.71	52.71
52.73	52.73
52.75	52.75
52.77	52.77
None	52.78
52.79/52.80	52.79
52.81	52.81
None	52.83
52.85	52.85
52.87	52.87
52.80	52.89
52.91	52.91
52.93	52.93
52.97	52.97
52.98	None
52.99	52.99
52.103	52.103
52.104	None
52.105	None
52.107	None
52.109	None
52.110	None
<i>Subpart D – RESERVED</i>	
<i>Subpart E – Standard Design Approvals</i>	
52.131	App. O, Introduction
52.133	None
52.135(a)	App. O, Paragraph 1
52.135(b)	App. O, Paragraph 2
52.135(c)	None
52.136	App. O, Paragraph 3
52.137	App. O, Paragraph 3
52.139	None
52.141	App. O, Paragraph 4
52.143	App. O, Paragraph 5
52.145(a)	App. O, Paragraph 5
52.145(b)	App. O, Paragraph 6
52.145(c)	App. O, Paragraph 7
52.147	None
<i>Subpart F – Manufacturing Licenses</i>	
52.151	App. M, Introduction
52.153(a)	App. M, Paragraph 8
52.153(b)	N/A
52.155	App. M, Paragraphs 2 and 4

52.156	App. M, Paragraph 4
52.157	App. M, Paragraphs 2, 4, 5, 6
52.158	App. M, Paragraph 3
52.159	App. M, Paragraph 1
52.161 [RESERVED]	N/A
52.163	App. M, Paragraph 1
52.165	App. M, Paragraph 1
52.167	App. M, Paragraphs 5,6,8, 10
52.169 [RESERVED]	N/A
52.171	App. M, Paragraphs 11 and 12
52.173	App. M, Paragraph 6
52.175	None
52.177	None
52.179	None
52.181	None
<i>Subpart G – RESERVED</i>	
<i>Subpart H – Enforcement</i>	
52.301	52.111
52.303	52.113

Table 2. Reverse Cross-References Current Part 52 vs. Proposed Part 52

<u>Existing Requirements</u>	<u>New Part 52 Rule</u>
<i>General Provisions</i>	
52.1	52.0
52.3	52.1
52.5	52.2
50.4*	52.3
52.9	52.4
50.7*	52.5
50.9*	52.6
50.12*	52.7
50.31*	52.8
50.53*	52.9
50.13*	52.10
52.8	52.11

*The existing part 52 portion of the General Provisions lists existing part 52 requirements as well as existing part 50 requirements (set out in bold print and with an asterisk) from which the corresponding proposed rule was derived.

Subpart A – Early Site Permits

52.11	52.12
52.13	52.13
52.15	52.15
None	52.16
52.17	52.17
52.18	52.18
52.19	None
52.21	52.21
52.23	52.23
52.24	52.24
52.25	52.25
52.27	52.27
None	52.28
52.29	52.29
52.31	52.31
52.33	52.33
52.35	52.35
52.37	None
52.39	52.39

Subpart B – Standard Design Certifications

52.41	52.41
52.43	52.43
52.45	52.41 and 52.45
None	52.46
52.47	52.47

52.48	52.48
52.49	52.45
52.51	52.51
52.53	52.53
52.54	52.54
52.55	52.55
52.57	52.57
52.59	52.59
52.61	52.61
52.63	52.63
<i>Subpart C – Combined Licenses</i>	
52.71	52.71
52.73	52.73
52.75	52.75
52.77	52.77
52.58	None
52.79	52.79 and 52.80
52.81	52.81
52.83	None
52.85	52.85
52.87	52.87
52.89	52.80
52.91	52.91
52.93	52.93
52.97	52.97
None	52.98
52.99	52.99
52.103	52.103
None	52.104
None	52.105
None	52.107
None	52.109
None	52.110
<i>Subpart D – VIOLATIONS</i>	
52.111	52.301
52.113	52.303
<i>Subpart E – Standard Design Approvals</i>	
52.131	App. O, Introduction
52.133	None
52.135(a)	App. O, Paragraph 1
52.135(b)	App. O, Paragraph 2
52.135(c)	None
52.136	App. O, Paragraph 3
52.137	App. O, Paragraph 3
52.139	None
52.141	App. O, Paragraph 4
52.143	App. O, Paragraph 5
52.145(a)	App. O, Paragraph 5
<i>APPENDIX M - Manufacturing Licenses</i>	

App. M, Introduction	52.151
App. M, Paragraph 1	52.159, 52.163, and 52.165
App. M, Paragraph 2	52.155 and 52.157
App. M, Paragraph 3	52.158
App. M, Paragraph 4	52.155, 52.156 and 52.157
App. M, Paragraph 5	52.157 and 52.167
App. M, Paragraph 6	52.157, 52.167 and 52.173
App. M, Paragraph 7	None
App. M, Paragraph 8	52.153(a) and 52.167
App. M, Paragraph 9	None
App. M, Paragraph 10	52.167
App. M, Paragraph 11	52.171
App. M, Paragraph 12	52.171
None	52.175
None	52.177
None	52.179
None	52.181

APPENDIX O - Standard Design Approvals

App. O, Introduction	52.131
None	52.133
App. O, Paragraph 1	52.135(a)
App. O, Paragraph 2	52.135(b)
None	52.135(c)
App. O, Paragraph 3	52.136 and 52.137
None	52.139
App. O, Paragraph 4	52.141
App. O, Paragraph 5	52.143 and 52.145(a)
App. O, Paragraph 6	52.145(b)
App. O, Paragraph 7	52.145(c)
None	52.147

REGULATORY ANALYSIS FOR FINAL RULE:
10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR
NUCLEAR POWER PLANTS"

Introduction

The Nuclear Regulatory Commission (NRC) is amending its regulations by revising the provisions applicable to the licensing, certifications, and approval processes for nuclear power plants in 10 CFR Part 52 and making necessary conforming amendments throughout the NRC's regulations. This is being done to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. The changes clarify the applicability of various requirements to each of the licensing processes (*i.e.*, early site permit, standard design approval, standard design certification, combined license, and manufacturing license).

This rulemaking is based on lessons learned during design certification and early site permit (ESP) reviews, and on discussions with stakeholders about the ESP, design certification, and combined license (COL) review processes. The NRC believes that this rulemaking action will improve the effectiveness and efficiency of the licensing and approval processes for future applicants.

This regulatory analysis has been prepared in accordance with the Regulatory Analysis Guidelines (RA Guidelines) of the NRC, NUREG/BR-0058, Revision 4, September 2004. The regulatory analysis consists of two parts. The first is an aggregate analysis of the final rule.

The second part is a screening review for disaggregation to identify any individual provisions whose costs are disproportionate to the potential benefits.

A. Aggregate Analysis-Summary of Results

Consistent with the RA Guidelines, the NRC performed an aggregate analysis of the rule. The analysis is based on a projected business scenario reflecting the NRC's expectations of 19 COL applications during the next 3 years and thereafter 1 COL applications per year would occur over the next 17 years. The net present value of the Part 52 rule modifications are estimated to result in savings to the industry of \$27,048 K and \$27,047 K using a 3-percent and a 7-percent discount rate, respectively. The provisions of the rule relating to Part 21 are estimated to result in net present value cost of \$2,504 K and \$1,862 K to the industry, using a 3-percent and a 7-percent discount rate, respectively. The net present value of the entire rule is estimated to result in a net savings to the industry of \$24,544 K and \$25,185 K at a 3-percent and a 7-percent discount rate, respectively. In addition, the rule is estimated to be a one time net present value savings to the NRC of \$8,424 K.

The NRC concludes that the costs of the rule are justified in view of the quantitative savings and evaluation and discussion of qualitative benefits in Section 5.1. The analysis measures the incremental value of the rule vis-a-vis the current rule. A summary of the analysis is presented in Section 5.2.

B. Screening Review for Disaggregation

The NRC also performed a screening review for disaggregation in accordance with Section 4.3.2 of the RA Guidelines to determine if there are provisions whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could mask the true impact. This analysis also responds to the Commission's direction in SRM-01-0134, dated July 23, 2001: "If there is a reasonable indication that a proposed change imposes costs disproportionate to the safety benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed changes for the purposes of backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR 50.109(a)(4)." The results of the analysis are documented in Section 5.2.

1. Statement of Problem and Objective

The NRC first published 10 CFR Part 52, "Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants" in April 1989. The NRC is revising these requirements through a reorganization, clarification, and rewrite of Part 52. The staff is also providing clarification and corrections to 10 CFR Parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52 (including Appendices A, B, C, and D), 54, 55, 72, 73, 75, 95, 140, 170, and 171. The rule reflects lessons learned from the Commission's experience in design certification and early site permit reviews and input from stakeholders, as appropriate, on the combined license process,

and corrects known errors and omissions. This action is expected to improve the effectiveness and efficiency of Part 52 licensing processes for future applicants. The major objectives of this rulemaking are to—

- increase regulatory efficiency
- reduce unnecessary regulatory burden
- address issues and incorporate lessons learned from the Part 52 licensing processes
- make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes
- address omissions and errors identified since the promulgation of Part 52
- clarify ambiguities in Part 52 to reflect the original intent of the NRC

This action will be applicable to future applicants for early site permits, design approvals, design certifications, combined license, and manufacturing license applications. It will not affect any current licensee under Part 52 since no license has yet been issued under Part 52. However, the action will affect applicants for completed design certifications and design approvals.

2. Background

A. Original Promulgation of Part 52

The NRC promulgated 10 CFR Part 52 on April 18, 1989 (54 FR 15386), to reform the NRC's licensing process for future nuclear power plants. The rule added alternative licensing processes in 10 CFR Part 52 for early site permits, standard design certifications, and combined licenses. The processes in 10 CFR Part 52 resolve safety and environmental issues early in licensing proceedings and enhance the safety and reliability of nuclear power plants through standardization. The rule also moved the licensing processes in Appendices M, N, O, and Q of 10 CFR Part 50 to 10 CFR Part 52. In 1992, the Commission revised Part 52 (December 23, 1992; 57 FR 60975) to reflect provisions of the Energy Policy Act of 1992, P.L. 102-486. Subsequently, the NRC certified four nuclear plant designs under Subpart B of 10 CFR Part 52—the U.S. Advanced Boiling Water Reactor (ABWR) Design (May 12, 1997; 62 FR 25827), the System 80+ design (May 21, 1997; 62 FR 27867), the AP600 design (December 23, 1999; 64 FR 72015), and the AP1000 design (January 27, 2006; 71 FR 4464) and codified these designs in Appendices A, B, C, and D of 10 CFR Part 52, respectively.

The regulations in Part 52 provide for the certification of standardized reactor designs, making it possible to use the same design information for the licensing of several plants, and provide for the issuance of a single license for both construction and operation, eliminating the need for two applications and two submittals of design information. Part 52 also provides for the approval of a nuclear power plant site in advance of the submission of any application for a construction permit for that site. The use of standardized designs allows a more focused review and the industry can transfer experience in maintenance and operation from one plant to

another more easily. In summary, the principal objective of Part 52 was to increase the effectiveness and efficiency of the licensing process for nuclear power plants by early resolution of issues.

B. July 2003 Proposed Rulemaking

The NRC planned to revise 10 CFR Part 52 after the first standard design certification reviews. In SECY-98-282, "Part 52 Rulemaking Plan," dated December 4, 1998, the staff proposed to initiate a rulemaking to revise Part 52. In a staff requirements memorandum issued on January 14, 1999, the Commission approved the NRC staff's plan for revising 10 CFR Part 52. After the issuance of SECY-00-0092, "Combined License Review Process," dated April 20, 2000, stakeholders at public meetings raised other licensing issues with 10 CFR Part 52 Subparts A and C (early site permits and combined licenses, respectively). The NRC obtained considerable stakeholder comments on its planned action through three public meetings on the proposed rulemaking, and two postings of draft rule language on the NRC's rulemaking Web site. On July 3, 2003, (68 FR 40026) the NRC published a proposed rule that would clarify and/or correct 10 CFR Parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52 (including Appendices A, B, and C), 54, 55, 72, 73, 75, 95, 140, 170, 171, revise portions of 10 CFR Part 52, and incorporate stakeholders comments.

3. Revised Proposed Rulemaking

Following the close of the public comment period on the July 2003 proposed rule, the NRC re-evaluated whether the proposed rule would meet the Commission's objective of improving the effectiveness of NRC's processes for licensing future nuclear power plants. First, public

comments identified several concerns about whether the July 2003 proposed rule adequately addressed the relationship between Part 50 and Part 52 and clearly specified the applicable regulatory requirements for each of the licensing and approval processes in Part 52. In addition, during the public comment period and thereafter, the NRC gained additional insights about early site permits as a result of the NRC's review of the first three early site permit applications. The NRC also had the benefit of public meetings with external stakeholders on the development of NRC guidance on early site permits and combined licenses. The NRC therefore decided that a substantial rewrite and expansion of the original proposed rulemaking, to include changes throughout the entire body of NRC regulations in Title 10, Chapter 1, was desirable so that the Agency may more effectively and efficiently implement the licensing and approval processes for nuclear power plants in Part 52.

Accordingly, the NRC developed a revised proposed rule for public comment that superseded the July 2003 proposed rule. The revised proposed rule contained a reorganization and rewrite of Part 52, and conforming changes throughout the NRC's regulations to improve the organization, format, and language of Part 52, and clarified the applicability of various technical and regulatory requirements throughout Title 10, Chapter 1, to each of the processes in Part 52 (early site permit, standard design approval, standard design certification, combined license, and manufacturing license).

The revised proposed rule was published in the *Federal Register* (71 FR 12781) on March 13, 2006. The public comment period for the rule expired on May 30, 2006. The NRC received 19 comment letters from industry stakeholders, other Federal agencies, and individuals during the public comment period. The NRC has considered and resolved all of the public comments

received during the comment period and has made modifications to the rule language, as appropriate.

This regulatory analysis considers two alternatives for amending the regulation for Part 52 and conforming changes throughout the 10 CFR.

4. Identification and Discussion of the Alternative Approaches

4.1 Alternative 1 - Take No Action

The no-action alternative is not to revise 10 CFR Part 52 and not to make conforming changes throughout 10 CFR. This action does not support the original intent of the Commission to revisit and update the rulemaking after gaining some experience with its use. Since the promulgation of 10 CFR Part 52 in April 1989, the NRC has approved four design certifications, and reviewed three early site permit applications. In addition, the Commission has held numerous public meetings to obtain input from stakeholders on the Part 52 regulatory processes.

The pros and cons of Alternative 1 are as follows:

Pros:

- The NRC will not incur the cost of the final rulemaking.

Cons:

- will not increase regulatory efficiency
- will not reduce unnecessary regulatory burden
- will not address issues and incorporate lessons learned from the Part 52 licensing processes
- will not make conforming changes throughout 10 CFR to reflect the revised licensing and approval processes
- will not address errors identified since the promulgation of Part 52
- will not clarify ambiguities in Part 52 to reflect the original intent of the NRC

4.2 Alternative 2 - Publish Revisions to Part 52

Alternative 2 reorganizes and rewrites Part 52 to incorporate lessons learned about Part 52 licensing and approval processes from reviewing design certification and early site permit applications, and from interactions with stakeholders on Part 52, including the combined license process. This rewrite includes conforming changes throughout 10 CFR to reflect the adoption of licensing, and regulatory approval processes in Part 52 and to clarify the relationship between requirements in Part 52 and other requirements in the regulations. Although the rule

is mainly focused on Part 52, the NRC made changes in many other parts of the regulations to clarify ambiguities and maintain consistency between the various licensing processes.

The pros and cons of Alternative 2 are as follows:

Pros:

- will increase regulatory efficiency
- will reduce unnecessary regulatory burden
- will address issues and incorporate lessons learned from the Part 52 licensing processes
- will make conforming changes throughout 10 CFR to reflect the revised licensing and approval processes
- will address errors identified since the promulgation of Part 52
- will clarify ambiguities in Part 52 to reflect the original intent of the NRC

Cons

- NRC will incur the cost of the final rulemaking.

The changes in this rulemaking can loosely be grouped in three categories: (I) conforming changes, format changes, reorganization, and clarifications that do not impose additional regulatory requirements, (ii) corrections, omissions, and additions that conform to the current NRC policy, and hence are not additional requirements, and (iii) changes that impose additional regulatory requirements that represent a departure from the old NRC policy. A regulatory analysis addresses only the incremental changes for measuring the impact of a rule.

Accordingly, this regulatory analysis addresses the changes described in the last group (iii).

The rule contains four changes that represent a departure from the old NRC policy and require further analysis—

- (1) update emergency preparedness requirements for a COL applicant referencing an ESP,
- (2) change the manufacturing licensing process concept; and require the development of inspection, testing, analyses and acceptance criteria (ITAAC) for the manufacturing licensing application,
- (3) implement quality assurance requirements per 10 CFR Part 50, Appendix B, for ESP applicants, and
- (4) implement reporting of defects requirements under Part 21 and Section 50.55(e) for design approval and design certification applicants.

Detailed discussions of these four changes are described below.

4.2.1 Update emergency preparedness requirements for a COL Applicant referencing an ESP

This amendment requires the COL applicant to update and correct emergency preparedness information approved in a reference ESP and to discuss whether the new information may materially change the bases for compliance with applicable NRC requirements. New information which materially changes the bases for compliance includes (1) information which substantially alters the bases for a previous NRC conclusion on the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, and (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions for emergency preparedness.

This amendment requiring a COL applicant to update the ESP's emergency preparedness information and the corresponding discussion of bases of compliance in the combined license application constitutes a change from the existing rule. The detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.1.

4.2.2 Change the manufacturing licensing process concept, require the development of ITAAC for the manufacturing license application

Appendix M of Part 52 currently sets forth the NRC's requirements for manufacturing licenses. Appendix M, which was first adopted by the NRC in 1973, provides for issuance of a license authorizing the manufacture of a nuclear power reactor to be incorporated into a nuclear power plant under a construction permit and operated under an operating license at a different location from the place of manufacture. Under the current licensing regime in Appendix M, the NRC does not approve a final reactor design to be manufactured before issuing the

manufacturing license. Rather, as in the Part 50 two-step licensing process, the NRC issues a manufacturing license based upon the review of a preliminary design equivalent to that provided in a construction permit application. Upon approval of the preliminary design and associated information, the NRC issues a manufacturing license authorizing the manufacture—but not the removal from the manufacturing site—of one or more nuclear power reactors. Thereafter, manufacturing can begin, although the NRC must approve the final design of the manufactured reactor by license amendment.

In view of the substantial re-organization and rewriting of 10 CFR generally, the NRC has reconsidered the efficacy of the current manufacturing license process in Appendix M and proposes substantial changes to enhance regulatory effectiveness and efficiency. The most important change in the manufacturing license concept proposed by the NRC is that a final reactor design must be submitted and approved before issuance of a manufacturing license. This approval of a final reactor design eliminates one step from the current two-step process of issuing a manufacturing license, and amending the license when a final design is submitted. The technical information required to be included in an application for a manufacturing license, as set forth in §§ 52.157 and 52.158, reflects both the expanded scope of approval to include the final design of the reactor to be manufactured, as well as lessons learned with respect to early site permits. Section 52.157 specifies the standard information required to be submitted in support of the design of a reactor. In addition, the application must address the provisions with respect to the demonstration by test, analysis, experience, or a combination thereof of simplified, inherent, passive, or other innovative means to accomplish safety functions, or the results of testing of a prototype plant, as set forth in revisions to § 50.43. Information which must be submitted as part of an application, but is not typically considered part of a final safety analysis report, is identified in § 52.158. This includes a probabilistic risk assessment (PRA),

proposed ITAAC to be used by the licensee that will construct and operate a nuclear power plant at its site using the manufactured reactor, and an environmental report for the manufactured reactor. The environmental report must address severe accident mitigation design alternatives (SAMDA), since the design approval phase is usually the most cost-effective stage for incorporating design features for addressing severe accidents.

The NRC is approving a reactor design for manufacture and the ITAAC for verifying that it has been acceptably manufactured and integrated into a nuclear power facility such that it can be safely operated in accordance with the approved manufactured reactor design, the NRC's regulations, and the requirements of the AEA.

The changes to the current Appendix M constitutes a change from the existing rule. The detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.2.

4.2.3 Implement quality assurance requirements per 10 CFR Part 50, Appendix B, for ESP applicants

The previous regulations do not explicitly require implementing a Part 50, Appendix B, program in support of an ESP application, and there is no requirement to describe the applicant's quality assurance program in an ESP application. However, under the previous Part 52 regulatory process, activities associated with site safety had to be controlled by QA measures sufficient to provide reasonable assurance that future safety-related systems, structures, and components (SSCs) of a nuclear power plant that might be constructed on the site will perform adequately in service. The regulations in 10 CFR 52.39, with certain specific exceptions, require the NRC to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a

construction permit or combined license referencing that ESP. Because of this finality, conclusions made during the ESP phase will be relied upon for use in subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an ESP is issued. Therefore, the level of quality used to control activities related to safety-related SSCs should be equivalent in substance in the ESP and COL phases. For these reasons, under the former rule, applicants had to apply quality controls to each ESP activity associated with the generation of design information for safety-related SSCs that were equivalent to those specified in Appendix B for similar activities.

The rule eliminates this ambiguity by the explicit requirement for an ESP applicant to establish and use quality control processes in accordance with 10 CFR Part 50, Appendix B, to conduct activities associated with an ESP. This constitutes a change from the existing rule. A detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.3.

4.2.4 Implement reporting of defects requirements under Part 21 for design approval and design certification applicants under Part 52

The reporting requirements in Section 206 of the Energy Reorganization Act of 1974 (ERA), as amended (1974 ERA) are incorporated in 10 CFR Part 21 and § 50.55(e). Section 50.55(e) sets forth the Section 206 reporting requirements applicable to holders of a construction permit. The proposed rule sets forth the NRC's proposals on how reporting requirements to implement Section 206 should be applied to applicants for design approvals and design certifications.

The NRC believes that the extensions of NRC's reporting requirements implementing Section 206 of the ERA to Part 52 licensing and approval processes should be consistent with

three key principles. First, the requirements should be legal obligations throughout the entire regulatory life of an NRC license, or a standard design approval or design certification. Second, defects must be reported whenever the information on potential defects will be most effective in ensuring the integrity and adequacy of the NRC's regulatory activities under Part 52 and the activities of entities subject to the Part 52 regulatory regime. Third, each entity conducting activities within the scope of Part 52 must develop and implement procedures and practices to ensure that it fulfills its Section 206 reporting obligations in an accurate and timely manner.

Reporting requirements for standard design approvals

A standard design approval represents the NRC staff's approval of a standard nuclear power reactor design or major portion thereof, which may then be referenced in a subsequent construction permit or combined license application. The NRC is imposing requirements to implement Section 206 on applicants for standard design approvals.

Reporting requirements for standard design certification

A standard design certification represents the NRC's approval by rulemaking of an acceptable nuclear power reactor design, which may then be referenced in a subsequent construction permit, operating license, combined license, or manufacturing license application. The NRC is imposing requirements to implement Section 206 on applicants for standard design certification.

5.1 Regulatory Impact—Cost-benefit of the action

Discussion in Section 4.2 identified four changes that represent a departure from previous NRC requirement. The cost-benefit analysis of the regulatory requirements associated with these four changes are based upon the NRC's assessment of the future business scenario as described below.

- Nineteen COL applications during the next 3 years and thereafter 1 COL applications per year would be submitted over the next 17 years. It is assumed that 4 of those 19 anticipated COL's would be referencing an ESP during the next 3 years and all 19 would be referencing design certification or design certification applications.
- One ESP application would be submitted over the next 3 years.
- Four design certifications would be submitted over the next 3 years.
- Two manufacturing licenses would be submitted in the next 20 years.

5.1.1 Update emergency preparedness requirements for a COL applicant referencing an ESP

A COL applicant referencing an ESP must include an update of the emergency preparedness information and a discussion of whether the new information materially alters the basis for compliance with the relevant requirements. This additional requirement constitutes a change from the previous rule. The cost-benefit analysis of this amendment using the above mentioned assumptions is as follows:

Costs to Applicant

The NRC assumed that four COL applications referencing an ESP would be submitted over the next 3 years.

The NRC estimates that it will take an applicant approximately 4 staff-months for a one-time cost of \$64 K (4 staff-months x 4 weeks/month x 40 hrs/week x \$100/hr) per application for updating the emergency preparedness information of an ESP.

The business scenario discussed above would result in a present value of approximately \$241 K at a 3-percent discount rate. With a 7-percent discount rate, the estimate would be \$224 K.

Costs to NRC

NRC will not incur additional costs for reviewing the updated emergency preparedness of a referenced early site permit, since the NRC needs to review the updated information anyway, particularly considering possibilities of significant lapse of time between the issuance of an ESP and the submittal of a COL.

Benefits to Applicant

The NRC believes that this amendment will reduce the overall regulatory burden of an applicant referencing an early site permit when reviewed in the context of the entire license review process, even though inclusion of the updated emergency preparedness information in the

referencing license application is an additional burden on the applicant. The NRC, in absence of the updated information, can not adequately assess the state of emergency preparedness of the COL application referencing an ESP. To determine the adequacy of the state of emergency preparedness, the NRC needs to request the information of the applicant. The applicant would spend considerably more resources to compile, analyze, and submit the information at a later date, as compared to providing the information in the referencing application. This delayed submittal would also prolong the license review time. It is estimated that it would take at least 50 percent more effort to submit the information after issuance of the referencing license application, since the submittal would necessitate reassembly of the team, require review of the existing documents and then update potentially large number of changes to the original submittal.

Using the above business scenario, updating of the emergency preparedness information during the license review phase would increase the applicant's effort by 50 percent, or \$96 K (4 NRC-months x 4 weeks/month x 40 hr/week x 1.5 x \$100/hr) per application. The same business scenario, at a 3-percent discount rate would result in a present value of approximately \$362 K. With a 7-percent discount rate, the estimate would be \$336 K.

Benefits to NRC

The review of the submittal will have no additional impact on the NRC for the reasons discussed in the cost section, but the schedule delays might have an impact. No efforts have made to quantify the impact of potential schedule delay.

5.1.2 Changes in manufacturing licensing process concept require the development of ITAAC for the manufacturing license application

This amendment requires that a final reactor design be submitted and approved before issuance of a manufacturing license. The approval of a final reactor design eliminates the current two-step regulatory process of issuing a manufacturing license based on preliminary design information and amending the license when a final design is submitted. Approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources to manufacturing the reactor. The technical information that must be included in an application for a manufacturing license reflects both the expanded scope of approval to include the final design of the reactor to be manufactured and the lessons learned during the ESP applications reviews.

The amendment eliminates preparation and Agency review of the preliminary license application, but requires an expanded license application that needs to include additional technical information, namely: a PRA, proposed ITAAC to be used by the licensee that will construct and operate a nuclear power plant at the site using the manufactured reactor, and an environmental report. Under the previous regulatory process, the PRA and the Environmental Report were integral parts of the license application, and hence inclusion of these in the final safety analysis report (FSAR), a part of the license application under the final rule, though not typical, are not considered an additional burden on the applicant. However, the development of ITAAC will be an additional burden. Under the final rule, elimination of the preliminary license application in itself will be a reduction in regulatory burden on both the applicant and the NRC.

The cost-benefit analysis of these proposed amendments is as follows:

Cost to Applicant

It is assumed that an application for a manufacturing license under the final rulemaking is equivalent to the first step of the existing process (*i.e.*, license application and corresponding design report except for the development of the ITAAC). In other words, the preparation of a manufacturing license application under the rule would involve the same amount of work as for the first step under the previous regulatory regime except for developing the ITAAC. The requirement for developing the ITAAC as a part of the manufacturing license application constitutes a change to the existing regulations and would impose additional regulatory burden on applicants for a manufacturing license.

Using the business scenario of two applications for manufacturing license, the NRC estimates that the applicant would incur a one time cost of \$4,160 K (10 staff-years x 2080 hr/year x \$100/hr x 2 applications) for the development of ITAAC.

In total, applicants would incur a one time costs of \$4,160 K.

Cost to NRC

The NRC estimates that the Agency would incur a one time cost for reviewing the ITAAC \$625 K (2 staff-years x 1776 hr/year x \$88/hr x 2 applications).

In total, the Agency would incur a one-time cost of \$625 K.

Benefit to Applicant

The applicant would not be required to prepare and submit an amendment of a manufacturing license under the rule, reduce regulatory burden compared to the two-step licensing process of the existing regulations. The NRC estimates that the elimination of one step would result in a one-time reduction of \$31,200 K (75 staff-years x 2080 hr/year x \$100/hr x 2 applications).

Benefit to NRC

The NRC estimates that the Agency would avoid the one-time cost of reviewing the license application \$9,377 K (30 staff-years x 1776 hr/year x \$88/hr x 2 applications). The NRC rate is based on estimated in-house data.

It should be noted, developing an ITAAC adds burden for the manufacturing license applicant, it does not add burden to the ultimate operator of a nuclear power generating facility since the ITAAC are developed before the issuance of the operating license and included in the operating license costs. Put another way, the additional burden of the ITAAC actually shifts the burden from one phase to another; *i.e.*, from operating license phase to the manufacturing license phase.

5.1.3 Implement Quality Assurance (QA) requirements per 10 CFR Part 50, Appendix B for ESP applicants

The rule requires an ESP applicant to implement a QA program under Part 50, Appendix B, to control ESP activities. The incremental burden of using the Part 50, Appendix B, program is shown below.

Costs to Applicant

The NRC estimates that each applicant would incur a one-time cost of establishing a Part 50, Appendix B, QA program of \$48 K (3 staff-months x 4 weeks/month x 40 hr/week x \$100/hr), and a cost of \$72 K (40 hr/month x 18 months x \$100/hr) to implement the QA program for the ESP activities for a total cost of \$120 K per applicant.

Using the above business scenario of one ESP application in the next 3 years at a 3-percent discount rate would result in a present value of approximately \$113 K. With a 7-percent discount rate, the estimate would be \$105 K.

Costs to NRC

The NRC would not incur any additional costs.

5.1.4 Implement reporting of defects requirements under Part 21 for design approval and design certification applicants

Part 21 implements the reporting requirements in Section 206 of the Energy Reorganization Act of 1974, as amended (1974 ERA). The Part 52 rule sets forth the Commission's requirement for applying reporting requirements implementing Section 206 of the 1974 ERA be applied to Part 52 licensing processes. The NRC's three key principles of reporting under Section 206 of the ERA are (i) a legal obligation exists throughout the entire regulatory life of a NRC license or a Part 52 approval, (ii) defects to be reported whenever the information on potential defects would be most "effective," and (iii) each entity conducting activities within the scope of Part 52 to develop and implement procedures and practices to ensure that it accurately and timely meets its Section 206 reporting obligations.

This amendment requires that applicants for standard design approvals and certifications make contractual agreements with contractors, subcontractors, consultants, and other suppliers of goods and services to notify them that they are subject to the NRC's regulatory requirements for developing and implementing reporting requirements and for timely and accurate reporting of any defects that they become aware of during and after completion of their scope of work. These requirements will impose additional regulatory burden on applicants and their contractors, subcontractors, consultants, and other suppliers of goods and services.

Each entity conducting activities under Part 52 is required to have a quality assurance (QA) program in place to control their specific activities. The QA programs of applicants and their contractors, subcontractors, consultants, and other suppliers must be modified to include procedures and practices for timely and accurate reporting of any defects that they become

aware of during and after completion of their scope of work. These programs must be capable of being implemented later when a product is referenced in a subsequent construction permit, an operating license, or a COL. The programs for reporting must also continue throughout the regulatory life of the referenced license.

The cost-benefit analysis of this proposed amendment is as shown below:

Costs to Applicant

Design Certification

The NRC estimates that the one-time cost for setting up the procedures for reporting of defects would be \$96 K (320 hr x 3 vendors x \$100/hr) per applicant.

Per the business scenario assumption of four design certification applications to be referenced by COL applicants during the next 3 years. This would result in a net present value of \$362 K at a 3-percent discount rate and \$336 K at a discount rate of 7-percent.

Also, the NRC estimates that it would require 180 hr/year for an estimated two contractors to report defects and maintain records for the regulatory life of a design certification, and it is assumed that four design certification applicants would be affected for a cost \$144 K (180 hr/year x 2 vendors x \$100/hr x 4 applicants) annually for the next 20 years for a net present value of \$2,142 K at a 3-percent discount rate and \$1,526 K at a 7-percent discount rate.

In summary, at a 3-percent discount rate it would cost \$2,504 K (362 K + 2,142 K) and \$1,862 K (336 K + 1,526 K) at a 7-percent discount rate.

Design Approvals

The estimated costs for a design approval would be the same as for design certification. However, the business scenario does not assume any design approval applications during the next 3 years. Therefore, the cost for design approval applicants is zero.

5.1.5 Final Rulemaking Costs

NRC

The NRC estimates that completing the final rulemaking would require a one-time cost of \$328 K (2.1 staff-years x 1776 hr/year x \$ 88/hr).

5.2 Aggregate Analysis

In accordance with the RA Guidelines, an aggregate analysis of all the significant provisions is shown in table below.

Provisions	Impact Type	Monetary Impact	
		Applicant	NRC
		All Values in Thousand \$'s	
		3%/7% @	3%/7% @
(1) Update of emergency preparedness for an ESP	Costs	-241/-224	0
	Savings	362/336	0
(2) Manufacturing license concept change, development of ITAAC	Costs	-4,160*	-625*
	Savings	31,200/31,200*	9,377/9,377*
(3) Implement QA program for ESP applicant	Costs	-113/-105	0
	Savings	0	0
(4) Implement reporting of defects (Part 21)	Costs	-2504/-1862	0
	Savings	0	
Total Part 21 amendments		-2504/-1862	0
Total Part 52 rulemaking amendments		27,048/27,047	8,752*
Total All Parts rulemaking amendments		24,544/25,185	8,752*
NRC Final rulemaking Cost	Costs	0	-328*
Net monetary impact at (3%/7% discount rate)		32,968/33,609	

Costs are negative, savings are positive.

@ Discount Rate

* Indicates One-time Occurrence

5.3 Disaggregation Analysis

The NRC has prepared an analysis of the impact of the changes (Attachment A) that identifies each provision affected by the rulemaking and determines whether it is appropriate to include each proposed change in the rule. This attachment details an analysis of each change and whether it is needed for the regulatory initiative to resolve the concerns and meet the stated objectives that are the focus of the regulatory initiative. The NRC also performed an analysis to identify any individual provision that could impose cost disproportionate to the benefits

attributable to each provision. The NRC has concluded that there are no provision whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could mask the impact of this rulemaking.

6. Decision Rationale

The NRC adopted Alternative 2. The basis for this rule is regulatory efficiency. Alternative 2 meets the objectives as stated in Section 1 - Statement of Objectives. A few salient features of the objectives are cited below.

Regulatory efficiency

- The regulatory requirements for license applications and supporting documents have been organized for consistency among the various licensing and regulatory processes of 10 CFR Part 52.
- The interconnection with other parts of Title 10 Chapter 1 are clearly described.
- Regulatory requirements for content of applications for regulatory approval are clearly expressed enabling applicants to address relevant issues completely, and provide sufficient information in license application and avoid burdensome and costly resubmittals of information during the license review.

Reduction of unnecessary regulatory burden

- Regulatory burden reduction of \$32,968 K at a 3-percent discount rate and \$33,609 K at a 7-percent discount rate

Address issues and lessons learned with respect to the Part 52 licensing process:

- Resolves design development issues early in the process ensuring early considerations and resolution of technical matters before a substantial commitment of resources.
- Increases regulatory stability and predictability, saving resources.
- Facilitates regulatory process of standardization of nuclear power plants.

Make conforming changes throughout 10 CFR Chapter 1 to reflect the revised licensing and approval processes.

Address errors identified since the promulgation of Part 52.

Clarify ambiguities in Part 52 to reflect the original intent of the NRC.

7. Implementation Schedule

This rule will become effective 30 days after publication of the final rule in the *Federal Register*.

Attachment A

Disaggregation Analysis

Section/Description	RE	RB	LL	CC	OR	CA
10 CFR Part 1						
1.4.3 Office of nuclear reactor regulation				X		
10 CFR Part 2						
Subpart A						
2.1 Scope				X		
2.4 Definitions				X		
2.100 Scope of parts				X		
2.101 Filing of applications	X			X		X
2.102 Administrative review of application				X		
2.104 Notice of hearing	X	X		X		
2.105 Notice of proposed action	X			X		
2.106 Notice of issuances				X		
2.109 Effect of timely renewal application	X			X		
2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues				X		
2.111 Prohibition of sex discrimination				X		
2.1202 Authority and role of NRC staff	X			X		
2.1211 Immediate effectiveness of initial decision directing issuance or amendment of licenses under part 61 of this chapter- Deleted						
Subpart B						
2.202 Orders	X			X		
Subpart C						
2.339 Expedited decisionmaking procedure	X			X		
2.340 Initial decision for facilities; immediate effectiveness of initial decisions; issuance of authorizations; permits and licenses	X	X		X		
2.390 Public inspections, exemptions, requests for withholding				X		
Subpart D						
2.400 Scope of subpart	X	X		X		
2.401 Notice of hearing on construction permit or combined license applications pursuant to appendix N of parts 50 or 52	X	X		X		
2.402 Separate hearings on separate issues; consolidation of proceedings	X	X		X		

Legend: RE - Increase Regulatory Efficiency; RB - Reduce Regulatory Burden; LL - Lesson Learned; CC - Conforming Changes throughout 10 CFR; OR - Correct Omissions and Error; CA - Clarify Ambiguous Language

Section/Description	RE	RB	LL	CC	OR	CA
2.403 Notice of proposed action on applications for operating licenses pursuant to appendix N of part 50	X	X		X		
2.404 Hearings on applications for operating licenses pursuant to appendix N of part 50	X	X		X		
2.405 Initial decisions	X	X		X		
2.406 Finality of decisions on separate issues	X	X		X		
2.407 Applicability of other sections	X	X		X		
Subpart E						
2.500 Scope of subpart				X		
2.501 Notice of hearing on application pursuant to Subpart F of Part 52 for a license to manufacture nuclear power reactors	X	X		X		
2.502 Notice of hearing on application under a construction permit for nuclear power reactor manufactured at the site at which the reactor to be operated- Deleted	X	X		X		
2.503 Finality of decision- Deleted	X	X		X		
2.504 Applicability of other sections- Deleted				X		
Subpart F						
2.600 Scope of subpart	X	X		X		
2.601 Applicability of other sections	X	X		X		
2.602 Filing fees	X	X		X		
2.603 Acceptance and docketing application for early review of site suitability issues in a construction permit proceeding	X	X		X		
2.604 Notice of hearing on application for early review of site suitability issues in a construction permit proceeding	X	X		X		
2.605 Additional considerations	X	X		X		
2.606 Partial decision on site suitability issues in a construction proceeding	X	X		X		
2.621 Acceptance and docketing of application for early review of site suitability issues in a combined license proceeding	X	X		X		
2.623 Notice of hearing on application for early review of site suitability issues in a combined license proceeding	X	X		X		
2.625 Additional considerations	X	X		X		
2.627 Partial decision on site suitability issues in a combined license proceeding	X	X		X		
2.629 Finality of partial decision on site suitability issues in combined license proceeding	X	X				
Subpart H						

Legend: RE - Increase Regulatory Efficiency; RB - Reduce Regulatory Burden; LL - Lesson Learned; CC - Conforming Changes throughout 10 CFR; OR - Correct Omissions and Error; CA - Clarify Ambiguous Language

Section/Description	RE	RB	LL	CC	OR	CA
2.800 Scope and applicability	X			X		X
2.801 Initiation of rulemaking	X			X		X
2.811 Filing of standard design certification application; required copies	X			X		X
2.813 Written communications	X			X		X
2.815 Docketing and acceptance review	X			X		X
2.817 Withdrawal of application				X		X
2.819 Denial of application for failure to supply information	X			X		X
10 CFR Part 10						
10.1 Purpose				X		
10.2 Scope				X		
10 CFR Part 19						
19.1 Purpose				X		
19.2 Scope	X			X		
19.3 Definition	X			X		
19.11 Posting of notices to workers	X			X		X
19.14 Presence of representatives of licensees and regulated entities, and workers during inspections	X			X		X
19.20 Employee protection				X		
19.31 Application for exemptions				X		
19.32 Discrimination prohibited				X		
10 CFR Part 20						
20.1002 Scope				X		
20.1401 General provisions and scope-Deleted				X		
20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits				X		
10 CFR Part 21						
21.2 Scope				X		
21.3 Definitions			X	X		
21.5 Communications				X		
21.21 Notification of failure to comply or existence of a defect and its evaluation				X		
21.51 Maintenance and inspections of records	X		X	X		
21.61 Failure to notify	X		X	X		
10 CFR Part 25						
25.35 Classified visits				X		
25.5 Definitions				X		
10 CFR Part 26						
26.2 Scope				X		
26.10 General performance objectives				X		

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Section/Description	RE	RB	LL	CC	OR	CA
10 CFR Part 50						
50.2 Definitions	x		x	x		x
50.10 License required	x		x	x		x
50.23 Construction permits				x		
50.30 Filing of application; oath or affirmation	x			x		
50.33 Contents of applications; general information.	x			x	x	
50.34 Contents of construction permits and operating license applications; technical information	x			x	x	x
50.34a Design objectives for equipment to control releases of radioactive material in effluents - nuclear power reactors				x		
50.36a Technical Specifications on effluents from nuclear power reactors	x		x	x		
50.37 Agreement limiting access to classified information				x		
50.40 Common standards	x			x		
50.43 Additional standards and provisions affecting class 103 licenses for commercial power	x			x		
50.45 Standards for construction permit, combined operating license				x		
50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors				x		
50.47 Emergency plans	x		x	x		x
50.48 Fire protection				x		
50.49 Environmental qualification of electric equipment important to safety for nuclear power plants				x		
50.54 Conditions of licenses	x		x	x		
50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses	x		x	x		x
50.55a Codes and standards				x		
50.59 Changes, tests, and experiments				x		
Section/Description	RE	RB	LL	CC	OR	CA
50.61 Fracture toughness requirements for protection against pressurized thermal shock events				x		
50.63 Loss of all alternating current power				x		
50.65 Requirements for monitoring effectiveness of maintenance at nuclear power plants				x		

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Section/Description	RE	RB	LL	CC	OR	CA
50.70 Inspections applicability to early site permit holders				X		
50.71 Maintenance of records, making of reports	X			X		
50.73 License event report system				X		
50.75 Decommissioning funding assurance		X		X		
50.78 Installation information and verification				X		
50.80 Transfer of license				X		
50.81 Creditor regulations				X		
50.90 Application for amendment of license or construction permit				X		
50.91 Notice for public comment; state consultation				X		
50.92 Issuance of amendment				X		
50.100 Revocation, suspension, modification of licenses, permits, and approvals for cause				X		
50.109 Backfitting				X		
50.120 Training and qualification of nuclear power plant personnel	X			X		
Appendix A to Part 50-general design criteria-nuclear power plants				X		
Appendix B to Part 50-Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	X		X	X		X
Appendix C to Part 50-A guide for the financial data and related information required to establish financial qualifications for construction permits and combined licenses				X		
Appendix E to Part 50- Emergency planning and preparedness for production & utilization facilities	X		X	X		X
Appendix I to Part 50- Numerical guides for design objectives and limiting conditions for operation to use the criterion "As low as is reasonably achievable" for radioactive material in nuclear light-water-cooled nuclear power reactors effluents				X		
Appendix J to Part 50-Primary reactor containment leakage testing for water-cooled reactors				X		
Appendices M and O to Part 50-Moved to Part 52				X		
Appendices S to Part 50- Earthquake Engineering Criteria for Nuclear power plants				X		
10 CFR Part 51						
51.17 Deleted				X		
51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements	X			X		
51.22 Criteria for categorical exclusion	X		X	X		

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Section/Description	RE	RB	LL	CC	OR	CA
51.23 Temporary storage of spent fuel after cessation of reactor operation-generic determination of no significant environmental impact				X		
51.26 Requirement to publish notice and conduct scoping process	X		X	X		
51.27 Notice of intent	X		X	X		
51.29 Scoping-environmental impact statement and supplement to environmental impact statement	X		X	X		
51.30 Environmental assessment	X	X		X		
51.31 Determinations based upon environmental assessment.	X	X	X	X		
51.32 Finding of no significant impact	X	X	X	X		
51.36 Finding of no new and significant information	X		X	X		
51.37 Draft finding of no new and significant information	X		X	X		
51.38 Final finding of no new and significant information	X		X	X		
51.39 Publication of draft and final finding of no new and significant information; limitation on NRC action	X		X	X		
51.45 Environmental report	X		X	X		
51.50 Environmental report -construction permit, early site permit, or combined license stage	X		X	X		
51.51 Uranium fuel cycle environmental data - Table S				X		
51.52 Environmental effects of transportation of fuel and waste-Table S-4.				X		
51.53 Post construction environmental reports	X			X		
51.54 Environmental report-manufacturing license	X	X		X		
51.55 Environmental report-design certification	X		X	X		
51.58 Environmental report-number of copies; distribution	X			X		
51.66 Deleted				X		
51.71 Draft environmental impact statement-contents	X			X		
51.75 Draft environmental impact statement-construction permit, early site permit, or combined license				X		
51.95 Deleted	X			X		
51.105 Public hearings in proceedings for issuance of construction permits or early site permits	X	X	X	X		
51.105a Public hearings in proceedings for issuance of manufacturing licenses	X	X		X		

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Section/Description	RE	RB	LL	CC	OR	CA
51.108 Deleted	X		X	X		
51.107 Public hearings in proceeding for issuance of combined licenses	X		X	X		
51.119 Publication of finding of no significant impact, or no new and significant information; distribution	X		X	X		
51.120 Availability of environmental documents for public inspection	X		X	X		
10 CFR Part 52						
52.0 Scope; applicability of 10 CFR Chapter 1 provisions	X		X	X		X
52.1 Definitions	X		X	X	X	
52.2 Interpretations	X			X		
52.3 Written communications				X		
52.4 Deliberate misconduct	X			X		
52.7 Specific exemptions	X			X		
52.8 Combining licenses	X			X		
52.9 Jurisdictional limits	X			X		
52.10 Attacks and destructive acts	X			X		
52.10a Information collection requirements-OMB Approval				X		
Subpart A Early Site Permits						
52.11 Scope of subpart				X		
52.13 Relationship to other subparts	X			X		X
52.15 Filing of application	X		X	X		X
52.16 Contents of application-general information	X			X		
52.17 Contents of application-technical information	X		X	X	X	X
52.18 Standard for review of application	X			X		
52.21 Administrative review of application; hearings				X		
52.24 Issuance of early site permits	X		X	X		
52.25 Extent of activities permitted	X			X		
52.28 Transfer of early site permits	X		X			
52.29 Application for renewal					X	
52.31 Criteria for renewal	X				X	
52.39 Finality of early site permit determination	X			X		
Subpart B Standard Design Certification						
52.41 Scope	X			X		
52.43 Relationship to Others	X		X	X		
52.45 Filing of application	X		X	X		X
52.46 Contents of application; general information	X			X		
52.47 Contents of application; technical information	X		X			X

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Section/Description	RE	RB	LL	CC	OR	CA
52.48 Standards for review of applications	X		X			X
52.54 Issuance of standard design certification	X		X			X
52.59 Criteria for renewal	X				X	
52.63 Finality of standard design certifications	X	X			X	
Subpart C Combined License						
52.73 Relationship to other subparts	X			X		
52.77 Contents of application; general information	X				X	
52.79 Contents of applications; technical information in final safety analysis report	X		X		X	X
52.83 Finality of referenced NRC approvals	X		X			X
52.85 Administrative review of applications; hearings	X					
52.87 Referral to the ACRS						
52.89 Environmental review- deleted & reserved	X					X
52.91 Authorization to conduct site activities	X					
52.97 Issuance of combined licenses.			X			
52.98 Finality of combined license; information requests.	X					
52.99 Inspection during construction.	X					X
52.103 Operation under a combined license	X					X
52.104 Duration of combined license	X					
52.105 Transfer of combined license	X					
52.107 Application for renewal	X					
52.109 Continuation of combined license	X					
52.110 Termination of license	X					
Subpart E Standard Design Approvals						
52.131 Scope of subpart	X					
52.133 Relationship to other subparts	X					
52.135 Filing of applications	X					
52.136 Contents of application; general information	X					
52.137 Contents of application; technical information	X					X
52.139 Standards for review of applications	X					X
52.141 Referral to the ACRS	X					
52.143 Staff approval of design	X					
52.145 Finality of the design approval	X					X
52.147 Duration of design approval	X					
Subpart F- Manufacturing Licenses						
52.151 Scope of subpart	X					
52.153 Relationship to other subparts	X					
52.155 Filing of applications	X	X				

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Section/Description	RE	RB	LL	CC	OR	CA
52.156 Contents of applications; general information	X	X				
52.157 Contents of applications; technical information in FSAR	X					
52.158 Contents of application: additional technical information	X					X
52.159 Standards for review of application	X					X
52.163 Administrative review of applications; hearings	X					
52.165 Referral to the ACRS	X					
52.167 Issuance of manufacturing license	X					
52.171 Finality of the manufacturing license; information requests	X	X				
52.173 Duration of manufacturing license	X					
52.175 Transfer of manufacturing license	X					
52.177 Application for renewal	X					
52.179 Criteria for renewal	X					
52.181 Duration of renewal	X					
Subpart H- Violations						
52.301 Violations				X		
52.303 Criminal penalties				X		
Appendices A, B & C Design Certifications for ABWR, System 80+, and AP600	X			X	X	X
Appendix O -Moved processes of Appendix O to Subpart E.				X		
Appendix — Moved Processes of Appendix M to Subpart F				X		
10 CFR Part 54						
54.1 Purpose				X		
54.3 Definition				X		
54.17 Filing of application				X		
54.27 Hearings				X		
54.31 Issuance of a renewed license				X		
54.35 Requirements during term of renewed license				X		
54.37 Additional records and record keeping requirement				X		
10 CFR Part 55						
55.1 Purpose				X		
55.2 Scope				X		
55.5 Communication				X		
10 CFR Part 72						
72.210 General license required				X		

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Section/Description	RE	RB	LL	CC	OR	CA
72.218 Termination of license				X		
10 CFR Part 73						
73.1 Purpose and scope				X		
73.50 Requirements for physical protection of licensed activities				X		
73.56 Personnel access authorization requirements for nuclear power plants				X		
73.57 Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to safeguards information by power reactor licensees.				X		
Appendix C				X		
10 CFR Part 75						
75.6 Maintenance of record and delivery of information, report, and other comments				X	X	
10 CFR Part 95						
95.5 Definition				X		
95.13 Maintenance of records				X		
95.19 Changes to security practices				X		
95.20 Grant, denial, or termination of facility clearance				X		
95.23 Termination of facility clearance				X		
95.31 Protective personnel				X		
95.33 Security education				X		
95.34 Control of visitors				X		
95.35 Access to matters classified as national security information and restricted data				X		
95.36 Access by representatives of the international atomic energy commission or participants in other international agreements				X		
95.37 Classification and preparation of documents				X		
95.39 External transmission of documents and material				X		
95.43 Authorized to reproduce				X		
95.45 Changes in classification				X		
95.49 Security of automatic data processing systems				X		
95.51 Retrieval of classified material following suspension or revocation of access authorization				X		
95.53 Termination of facility clearance				X		
95.57 Reports				X		
95.59 Inspections				X		
10 CFR Part 140				X		

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Section/Description	RE	RB	LL	CC	OR	CA
140.2 Scope				X	X	
140.10 Scope				X		
140.11 Amounts of financial protection for certain reactors				X		
140.12 Amount of financial protection required for other reactors				X		
140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under Part 52.				X		
140.20 Indemnity agreements and liens				X		
140.31 Scope				X		
140.93 Appendix C				X		
140.96 Appendix F				X		
10 CFR Part 170				X		
170.2 Scope				X		

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Comment Summary Report

Final Rule for 10 CFR Part 52 Licenses, Certifications, and Approvals for Nuclear Power Plants

October 11, 2006

Division of New Reactor Licensing
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001



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Appendix A: Comment Numbers, Commenter Names and Organizations, and Issues
Commented On

Acronyms and Abbreviations

ACRS	Advisory Committee on Reactor Safeguards
AEA	Atomic Energy Act
APA	Administrative Procedure Act
ASME	American Society of Mechanical Engineers
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
COL	combined license
COLA	combined license application
CP	construction permit
CWA	Clean Water Act
CZMA	Coastal Zone Management Act
DC	design certification
DCD	design control document
DCR	design certification rule
EIS	environmental impact statement
EP	emergency plans
ERA	Energy Reorganization Act
ESP	early site permit
FDA	final design approval
FR	<i>Federal Register</i>
FSAR	final safety analysis report
GSI	generic safety issues
ITAAC	inspections, tests, analyses, and acceptance criteria
LWR	light water reactor
LWAs	limited work authorizations
ML	manufacturing license
NEI	Nuclear Energy Institute
NEPA	National Environmental Policy Act
NOPR	Notice of Proposed Rulemaking
NRC	Nuclear Regulatory Commission
PPE	plant parameter envelope
PRA	probabilistic risk assessment
QA	quality assurance
SAMDAs	severe accident design mitigation alternatives
SDA	standard design approval
SRM	staff requirements memorandum
SRP	standard review plan
SSAR	site safety analysis report
SSCs	structures, systems, and components
U.S.	United States of America
USC	U.S. Code
X/Q	atmospheric dispersion factors

Preface

This document summarizes comments the U.S. Nuclear Regulatory Commission (NRC) received in response to publication of a proposed rule on Licenses, Certifications, and Approvals for Nuclear Power Plants in the *Federal Register* (FR) on March 13, 2006 (71 FR 12782). The notice requested comments on 15 specific questions and on NRC's proposed revisions to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52 and on proposed changes throughout the Commission's regulations to clarify the applicability of various requirements to each of the processes in Part 52 (*i.e.*, early site permits, standard design approvals, standard design certifications, combined licenses, and manufacturing licenses). The NRC received 19 comment letters during the public comment period which ended on May 30, 2006. The NRC also received 3 comment letters submitted well after the public comment period closed. Although the NRC did not specifically address the 3 late comment letters, the majority of the comments in these 3 letters were already addressed by other commenters and, therefore, are discussed in this report. For each comment letter, the NRC assigned a sequential number, and then also assigned numbers to topics or issues within the document. This report is generally structured to match the outline of the final rule Federal Register Notice.

Appendix A to this report contains a table that identifies the comment number, commenter name and organization, and the issues—by summary section number—on which they commented.

Summarized Comments Received By Issue

- 1 Background (Development of 2003 & 2005 Proposed Rules)
- 2 Overview of Public Comments (summary & pointers to other sections)

Reorganization of Part 52 and Conforming Changes in the NRC's Regulations

Comments 007-11, 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017:¹ Several commenters identified four types of changes in the proposed rule: (1) changes to Part 52 to copy some requirements and contain references to other requirements from Part 50 and other regulations, (2) changes to Part 50 and other regulations to contain references to Part 52, (3) changes to Part 52 that would delete the existing provisions in 10 CFR 52.83 and modify other regulations such as 10 CFR 52.81 to delete the statement that Part 50 and other regulations apply to the extent “technically relevant,” and (4) 10 CFR 52.0, which contains general provisions regarding the applicability of other parts. The commenters stated that they understood the changes were not intended to impose new requirements on Part 52 applicants, but instead to clarify which requirements were applicable to Part 52 applicants (*i.e.*, the changes were not meant to be substantive). The commenters stated that they nevertheless had a number of concerns with the proposed rule. They noted proposed § 52.0(b) stated that unless otherwise specifically provided for, the regulations in 10 CFR Chapter 1 would apply to a holder of, or applicant for, an approval, certification, permit, or license. The commenters believed this sentence was “unnecessary” and conflicted with other provisions in § 52.0(b), which stated that only the “applicable” provisions applied. The commenters also expressed concern that the NRC may have missed applicable requirements or provisions (*e.g.*, past mistakes in Part 171 that were corrected in the Notice of Proposed Rulemaking). The commenters stated that in order to account for such inadvertent oversights by the NRC and reviewers, it was “critical” that Part 52 contain language similar to that currently in §§ 52.81 and 52.83 (*i.e.*, “applicable as technically relevant” language to encompass regulations meant to apply to Part 52 applicants that are not specifically addressed in the proposed rule). The commenters expressed the belief that no downside existed to retaining this existing language.

NRC Response: While the Commission understands the concerns of the commenters, the Commission declines to adopt the solution presented by one of the commenters. As that commenter recognizes, the Commission's approach in the proposed rule was to: (i) adopt regulatory language that made clear that all “applicable” Commission requirements throughout 10 CFR Chapter 1 apply to holders or applicants for Part 52 licenses and approvals (first sentence of § 52.0(b)), and to the Part 52 licenses and approvals themselves (second sentence of § 52.0(b)); and (ii) conform the language of the Commission's regulatory language, wherever necessary, to explicitly delineate what requirements are “applicable” to the licensees, applicants, licenses and approvals. The commenter' correctly adduces the potential weakness

¹Commenters 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017 all fully endorsed and supported the Nuclear Energy Institute's (NEI's) comments of May 30, 2006. Therefore, all of these commenters are included in each of NEI's May 30, 2006 comments (comment number 007). For simplicity, these comment numbers are not repeated in this document for each comment.

in this approach, viz., that there may be an inadvertent failure by the Commission to identify a necessary conforming change in the one or more of the Commission's regulations.

However, in the Commission's view, the proposed solution presented by one of the commenters presents more significant problems with respect to regulatory certainty and stability. If the Commission were to adopt the commenter's suggestion of inserting the phrase, "technically relevant," into §§ 52.0, 52.58, 52.81, 52.139, and 52.159, this would re-introduce to some extent the problem, present in the original Part 52 rule, of determining whether any particular Commission requirement in 10 CFR Chapter 1 is, in fact, "technically relevant" to any particular licensee, applicant, license or approval. This could lead to unnecessary disputes between an applicant and the NRC whether a particular NRC requirement, silent on its face as to its applicability to that applicant, nonetheless is "technically applicable" and therefore must be complied with. A licensee's failure to comply with what NRC regards as "technically relevant" requirements would be the focus of enforcement. Finally, interested persons in a licensing proceeding would be able to request a hearing on the basis that a particular "technically relevant" regulation was neither addressed in the application nor otherwise complied with by the applicant.

Inasmuch as the commenter's proposed suggestion would not effectively address the earlier-identified concerns on the ambiguity of the term, "technically relevant," the Commission declines to adopt the commenters' proposed changes in the final Part 52 rule. The Commission believes that any inadvertent failure by the Commission to properly delineate the applicability of a provision in the Commission's regulations can be dealt with on a case-by-case basis through rulemaking or Commission order (e.g., under the provisions of 10 CFR 2.335).

4 Responses to Specific Requests for Comments (Questions A-O)

4.1 Question 1: General Provisions - Create new Subpart in Part 50 – not update Part 52

Comment 007-88: Commenters stated the clarity of the regulations would not be enhanced by moving provisions from Part 52 to Subpart 50. The commenters argued that in addition to not eliminating existing confusion, such a content shift would create new confusion because current documents referencing Part 52 would become "obsolete."

NRC Response: The Commission has decided not to transfer provisions from Part 52 to a new subpart in Part 50, inasmuch as: (i) no commenter favored transferring provisions from Part 52 to a new subpart in Part 50, (ii) either approach is legally equivalent, and (iii) nearly 17 years has passed since the Commission adopted the approach of establishing early site permits, standard design certifications, and combined licenses in a new Part 52, and a reorganization of the regulations at this time may engender confusion without any compensating benefits in clarity, regulatory stability and predictability, or efficiency.

4.2 Question 2: EP Major Features - Revise options for proposing major features of emergency plans in ESP process

Comment 007-89: Several commenters suggested the current process for addressing major features of emergency plans (EP) in the early site permit (ESP) be retained without modification. Commenters expressed a fear that the loss of this option would result in a loss of flexibility to achieve “finality” without producing a comprehensive EP. Commenters identified a need to clarify the definition of “major features” of the EP to make it less restrictive. Commenters [believed that the approved major features were acceptable elements of a “complete and integrated emergency plan that would be considered later.” Commenters believed the information should not be reviewed again during the COL process, which would instead focus on (1) the integration of these major features with information necessary to support the “reasonable assurance finding”, and (2) the updating of EP information required by § 52.39 (b). Commenters referenced comments made in excerpt 007-16.

NRC Response: Based on commenters’ feedback, the NRC has decided to retain the current process for addressing major features of emergency plans in an ESP without modification. The NRC agrees that it should clarify the definition of major features and has done so by adding the definition suggested by the commenters to § 52.1 in the final rule.

4.3 Question 3: Appendix Q - Retain the Early Site Review Process

Comments 007-43, 007-90: Commenters expressed concern about the loss of flexibility to assess site suitability that would result from the deletion of Appendix Q. Commenters believed that Appendix Q (in conjunction with Subpart F of 10 CFR Part 2) was important for allowing “critical path issues” to be reviewed prior to submission of a Combined License Application (COLA) in instances where prior completion of an ESP was not feasible. Commenters argued for the efficiency of Appendix Q and Subpart F because only applicant-selected issues would be reviewed during these processes. Commenters recommended changes be made to specifically allow ESP and COL applicants to reference an early site review conducted in accordance with Appendix Q or Subpart F. The commenters stated that the NRC should not delete the option for a Part 52 applicant to reference a review performed under Appendix Q for reasons mentioned in excerpt 007-90 (summary Sections 4.3, 5.3, and 4.4.22).

NRC Response: Commenters expressed concern about the loss of flexibility to assess site suitability that would result from the deletion of Appendix Q. Commenters believed that Appendix Q (in conjunction with subpart F of 10 CFR Part 2) was important for allowing “critical path issues” to be reviewed prior to submission of a combined license application (COLA) in instances where prior completion of an ESP was not feasible. Commenters argued for the efficiency of Appendix Q and subpart F because only applicant-selected issues would be reviewed during these processes. Commenters recommended changes be made to specifically allow ESP and COL applicants to reference an early site review conducted in accordance with Appendix Q or subpart F. The commenters stated that the NRC should not delete the option for a Part 52 applicant to reference a review performed under Appendix Q.

In response to commenters concerns, the NRC has decided not to remove Appendix Q from Part 50 or Part 52 in the final rule. Appendix Q has been included in Part 52 in the final rule and conforming changes have been made to make it available for use by prospective early site

permits and combined license applicants. Such applicants will have the same option for early resolution of site suitability issues as is currently available to construction permit applicants. This will provide early site permit and combined license applicants with additional flexibility to seek early resolution of issues.

The NRC also agrees that § 2.101(a-1) and subpart F of Part 2 should be modified to allow applicants for early site permits and combined licenses under Part 52 to take advantage of those provisions. Both § 2.101(a-1) and subpart F have been revised in the final rule, albeit somewhat differently than the approach recommended by the commenter. Inasmuch as the revisions are to the Commission's rules of procedure and practice, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

4.4 Question 4: ML Finality - Provide future option for NRC approval of ITAAC for manufacturing

Comment 007-91: Commenters requested that applicants for manufacturing licenses be allowed, but not required, to use inspections, tests, analyses, and acceptance criteria (ITAAC) to ensure that an “as-manufactured plant conforms to the important design characteristics specified in the application for the manufacturing license.”

NRC Response: The Commission has decided to defer consideration of this alternative, for several reasons. First, one commenter's proposal to allow ITAAC for assuring that the as-manufactured reactor “conforms to the important design characteristics specified in the application for the manufacturing license, “ raises questions about what those “important design characteristics” might be, and why the ITAAC would be so narrowly limited. The Commission did not receive any in-depth comments presenting arguments one way or the other on the feasibility of developing such ITAAC, and the potential legal implications of, and technical considerations with respect to, such a finding by the manufacturer. Moreover, it is clear that any regulatory process that the Commission may adopt in rulemaking would require further opportunity for public comment, and therefore could not be adopted in a final Part 52 rulemaking without substantial delay. In light of the lack of any near-term interest by any entity in obtaining a manufacturing license, the Commission has decided not to adopt any provisions for ITAAC governing approval of manufacturing in the final Part 52 rule. However, the Commission would address these issues in a timely fashion if raised in a rulemaking petition which demonstrated near-term interest in an application for a manufacturing license.

4.5 Question 5: 50/52 Segregation - Remove provisions allowing a construction permit applicant to reference an ESP or DC

Comment 007-92: Commenters stated the deletion of provisions allowing a construction permit applicant to reference an ESP or DC was ill-advised given the untested nature of the COL process and the resulting need to retain “regulatory flexibility” to deal with unexpected issues. As a contingency plan to buffer against difficulties with COL process, the commenters proposed the addition of a provision in Part 50 to specify that a construction permit applicant could reference a DC without the inclusion of ITAAC. The commenters suggested that in these instances, “the operating license proceeding would need to find under 10 CFR 50.57(a)(1) that construction of the facility has been substantially completed, in conformity with the construction

permit and the application as amended, the provisions of the Act, and the rules and regulations of the Commission.” Commenters stated that standard design should be final and not open to review in the construction permit and operating licenses proceeding. Commenters requested a construction permit applicant be able to reference an ESP in the same way as would a COL applicant.

NRC Response: Based on commenters response to this question and further consideration of the issue, the NRC has decided not to make any changes in the final rule to delete provisions allowing a construction permit applicant to reference an early site permit or a design certification. The NRC has also decided not to add any additional provisions to Part 50 or Part 52 to address a construction permit applicant’s ability to reference either a design certification or an early site permit. The NRC believes it is unlikely that such a construction permit application will be submitted and the NRC will handle any such applications on a case-by-case basis. If such an application were submitted, there are many process issues that would need to be carefully considered and would need to be discussed with the applicant.

4.6 Question 6: Fuel Load Date - Require notification of NRC of the scheduled date for fuel loading

Comment 007-93: Commenters stated that a rule change was unnecessary to address the NRC notification because a guidance from the NRC would be sufficient. Commenters suggested that following the initial notification, a licensee should be required to submit a follow-up 30-day notification only if the schedule in the prior notification had changed.

NRC Response: The NRC has decided to amend § 52.103(a) in the final rule to ensure that the combined license holder will notify the NRC of its scheduled date for initial loading of fuel into a plant no later than 270 days before the scheduled date, and will notify the NRC of updates to its schedule every 30 days thereafter. The notification will facilitate timely NRC publication of the notice required under § 52.103(a), completion of hearings within the time frame allotted under § 52.103(e), and completion of any Commission determinations on petitions filed under § 52.103(f). The NRC believes that update notifications, when the schedule has not changed, will not be burdensome.

4.7 Question 7: Op Programs - Additional required operational programs that should be described in a COL

Comment 007-94: Commenters believed that requirements for operational programs were sufficient as proposed, and that no additional operational programs needed to be described in the COL application.

NRC Response: The NRC does not agree that no additional operational programs need to be described in a COL application. During the preparation of the final rule, the NRC discovered that several of the operational programs listed in SECY-05-0197 were not addressed in proposed § 52.79. To ensure the list of requirements for the contents of applications is complete, the NRC is adding several new provisions to address operational programs in the final rule. Specifically, the NRC is adding requirements to § 52.79 for COL applicants to include a description of: (1) the process and effluent monitoring and sampling program required by Appendix I to 10 CFR Part 50 [§ 52.79(a)(16)(ii)]; (2) a training and qualification plan in

accordance with the criteria set forth in Appendix B to 10 CFR Part 73 [§ 52.79(a)(36)(ii)]; (3) a description of the radiation protection program required by § 20.1101 [§ 52.79(a)(39)]; (4) a description of the fire protection program required by § 50.48 [§ 52.79(a)(40)]; and (5) a description of the fitness-for-duty program required by 10 CFR Part 26 [§ 52.79(a)(44)]. During the preparation of the final rule, the NRC also noticed that it had not completely implemented the Commission's direction regarding the treatment of operational programs in a COL application because it had failed to add requirements to address program implementation in its revisions to § 52.79(a). Therefore, in the final rule, the NRC has added requirements to address the implementation of all operational programs required to be described in a COL application. This is consistent with the Commission's direction to the staff in SRM-SECY-02-0067 that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application [emphasis added].

4.8 Question 8: Backfitting - Reproduce backfitting requirements in Part 52

Comment 007-95: Commenters stated that NRC's alternative approach to addressing backfitting was unnecessary to clarify the application of the backfitting rule to Part 52 actions. Commenters stated that the proposed rule included adequate references to § 50.109 and in the various Subparts of Part 52, making replication of this language elsewhere unnecessary. If the NRC deemed the inclusion of such information necessary, several commenters suggested each Subpart in Part 52 include its own standards for backfitting to avoid confusion.

NRC Response: The Commission has decided to revise § 50.109 to include the conforming changes, rather than adopting a backfitting provision in Part 52, inasmuch as no commenter favored the alternative approach of adopting a backfitting provision in Part 52, and both approaches are legally equivalent.

Comment 013-4: A commenter expressed support for the NRC's proposed Part 52 protection against backfitting. The commenter supported the NRC's proposed language for 10 CFR 50.109 cross-references to applicable provisions of Part 52, which would provide backfitting protections for the Part 52 licensing process.

NRC Response: The Commission has decided to revise § 50.109 to include the conforming changes, rather than adopting a backfitting provision in Part 52, inasmuch as no commenter favored the alternative approach of adopting a backfitting provision in Part 52, and both approaches are legally equivalent.

4.9 Question 9: ESP Updates - Updating environmental and emergency preparedness information

Definition of New and Significant Information

Comments 002-10, 002-12, 002-13, 002-13, 002-14, 002-15, 002-16, 002-17, 002-96: Several commenters were opposed to wording in the text of proposed § 51.50(c)(1) that would require COL applications to include, "any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit environmental impact statement." Commenters stated the COL Application Environmental

Report should not be required to identify all new information regarding previously considered issues. Commenters explained that, consistent with the process and practices used for license renewal, a COL applicant should only provide information about a previously considered environmental issue if it is both new and significant, not simply different from or in addition to previously presented information. Commenters were concerned that the concept of what is “new” was being tied exclusively to what information was in the ESP EIS. They supported a more sharply defined version of what constituted “new” than what existed in proposed §§ 51.50(c)(1) and 52.39(c). Commenters stated the NRC proposed definition would: (1) result in unnecessary and duplicative work for COL applicants and the NRC staff, (2) introduce inefficiencies into the licensing and hearing process, (3) potentially expand any associated hearing, and (4) undermine the value of the ESP. Commenters expressed concern that a party to a COL proceeding could potentially litigate whether the conclusions in the EIS would be changed by any information—any study, any report, any opinion, or any alleged facts—not explicitly discussed in the EIS, as long as that party met the pleading requirements of basis and reasonable specificity, and even if the information was addressed for ESP (but not documented in the EIS).

Commenters requested that at a minimum, no information be deemed “new” if it was considered in preparing the Environmental Report or EIS (as would be evidenced by references in those documents, request for additional information responses, comment letters, and the like), or if it was generally known or publicly available (such as information in reports, studies and treatises) during preparation of the EIS. Commenters advised that the Part 52 final rule and Supplementary Information be amended to reflect a more appropriate definition of “new” information.

NRC Response: The NRC agrees with the commenters. The NRC has removed wording requiring that COL applicants referencing an ESP include “any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit environmental impact statement.” Instead, the NRC has modified § 51.50(c)(1) (and related provisions) in the final rule to require that COL applicants referencing an ESP include any significant new information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding. The NRC agrees that a COL applicant should only provide information about a previously resolved environmental issue if it is both new and significant. The final rule states that, in the context of a combined license application that references an early site permit, the NRC defines the term “new” in the phrase “new and significant information” as any information that was not considered in preparing the early site permit environmental report or EIS (as may be evidenced by references in these documents, applicant responses to NRC requests for additional information, comment letters, etc.) or if it was generally known or publicly available during the preparation of the EIS (such as information in reports, studies and treatises). This new information may or may not be significant. For an issue to be significant, it must be material to the issue being considered, i.e., it must have the potential to affect the NRC staff’s evaluation of the issue.

Process for Identifying New and Significant Information

Comments 002-9, 002-11, 002-12, 002-13, 002-14, 002-15, 002-16, 002-95: With respect to ESP environmental information, commenters stated that a COL applicant should have processes for identifying “new and significant” information that causes an adverse change to an

ESP EIS conclusion. The commenters stated that the processes for identifying information and for evaluating whether that information would have an adverse impact on the conclusions in the ESP EIS should be available for the NRC audit at the COL applicant's facilities in a manner comparable to the process used for license renewal. The commenters did not believe that this information should be required or codified in NRC regulations because it was beyond the scope of 10 C.F.R. §§ 52.79(a)(1) and 52.89.

Comment 007-18: Several commenters suggested that the proposed requirement in § 51.50(c)(1) to have COL applications include new and significant information is unnecessary and should be deleted. The commenters do not believe a regulatory requirement is needed for COL applicants when no such requirement has been needed for license renewal.

NRC Response: The NRC disagrees with the majority of the comments. The NRC believes that a combined license (COL) applicant who references an early site permit (ESP) must have a process to identify any significant new information for issues that were resolved in the ESP proceeding. The NRC also believes that its review of environmental information provided in a COL application that references an ESP will be significantly enhanced by having a description of the applicant's process used to identify new and significant information regarding the NRC's conclusions in the early site permit environmental impact statement.

This belief is based on the quality and level of detail of information that was used in the earlier analysis. For license renewal, the NRC performed the analysis of environmental effects during the renewal period for each of the operating plants and for those plants with a construction permit for a specific design; the NRC also had the benefit of the operating experience of over 100 units for an extended period of time to support its analyses. For new plants where the environmental impacts of construction and operation are resolved in the ESP proceeding, the conclusions are based on analytical methods and assumptions regarding the design, construction and operation of the facility. However, some of the information about the design, construction practices, and proposed operations is not well known at the time of the ESP application. For these reasons and based on its experience in the review of environmental information in license renewal applications, the NRC believes that having a description of the process for identifying new and significant information in COL applications will enhance the effectiveness and efficiency of the licensing process by providing greater focus to the NRC's subsequent audit of the COL applicant's process for identifying new and significant information. In evaluating whether there is new and significant information at the COL stage, the NRC staff will independently be responsible for the reliability of all information used. Consequently, if the NRC is to rely upon information presented by the proponent of the action, then it must have confidence in the measures taken by the applicant to identify new and significant information that may have arisen during the intervening period between the ESP proceeding and the COL application.

Updating ESPs

Comments 007-96, 011-19: Several commenters believed an ESP holder should not be required to update the information in the ESP application. These commenters stated that the proposal to require updating would add an unnecessary additional level of review (and possibly hearings) with little or no additional benefit (*i.e.*, the COL applicant would still be under the obligation to update the information provided by the ESP holder). Commenters contended that

an updating requirement would only serve to erode the finality and certainty provided by the ESP, thereby defeating one of the purposes of an ESP. Commenters also believed that an updated requirement would run counter to NRC regulations. Commenters stated that while the ESP is in effect, the NRC cannot change or impose new requirements, including emergency planning requirements, unless it determines that a modification is necessary either to bring the permit or the site into compliance with the NRC's regulations and orders applicable and in effect at the time the permit was issued, or to assure adequate protection of the public health and safety or the common defense and security. Commenters argued that the proposed 18-month updating requirement may not be feasible. A commenter gave the following example, "under the NRC's current schedule for the existing ESP applications for North Anna and Grand Gulf, the ESPs will not be issued until 2007, shortly before the planned COL applications for those sites. This would result in insufficient time for the updating envisioned by the NRC, and it would be unfair to those applicants to require them to delay their COL applications to accommodate the updating process. Additionally, the proposed updating process would be inconsistent with 10 CFR 52.27(c), which permits a COL application to reference an ESP application."

Several commenters agreed with NRC's proposal to provide the ESP holder with the option of requesting an ESP amendment in order to resolve issues that were not addressed at the ESP stage or to achieve finality on updated information. These commenters also suggested that a COL applicant should be able to reference an application for an ESP amendment that is pending approval by the NRC similar to the process that already exists in 10 CFR 52.27(c).

Several commenters expressed the belief that a COL applicant should be able to make changes or updates to ESP emergency planning information without NRC approval in accordance with the criteria in 10 CFR 50.54(q) just as the remaining safety information can be revised under 50.59 once it has been reviewed and approved (see excerpt 007-46 in summary Section 5.3.2 for further discussion of this topic). The commenters also stated that this revised information should not be considered as an "amendment" submitted under 50.90 for review and approval, but rather should be considered to be information equivalent to that provided under § 50.71(e) for information.

NRC Response: The NRC agrees with the commenter that ESP holders should not be required to update the information in the ESP application. NRC also agrees with the commenter that the ESP holder should have the option of requesting an ESP amendment in order to resolve issues not previously addressed, and has added rule language to Sections 50.90 through 50.92 to include ESP holders. The NRC agrees that a COL applicant can use the authority under §52.27(c) to reference a site for which an ESP application had been docketed but not approved; if an amendment to the ESP is granted, it would then be part of the pending ESP application. The response to the comment concerning changes to ESP emergency planning information using §50.54(p) is discussed in Section 5.3.2 of this report.

4.10 Question 10: Living Probabilistic Risk Assessment (PRA) - Update of PRA and schedule for update

Comment 007-97: Several commenters noted the NRC had stated that PRA scope and methods should be addressed in guidance, not in regulations (SRM on SECY-05-0203). Commenters supported the notion that PRA update frequency be addressed in guidance rather

than regulations. Commenters indicated a frequency of once every two operating cycles would be reasonable and consistent with existing requirements in 10 CFR 50.69(e).

Additionally, commenters stated the plant-specific PRA used to support a COL application that references a design certification would essentially be the design certification PRA. Commenters expressed the belief that the plant-specific PRA would be updated to be consistent with the PRA scope and quality standards six months before the COL was issued as plant-specific design and as-built information was developed during construction. Commenters argued that this would allow (1) an updated plant-specific PRA that was representative of the as-built plant to be completed, and (2) an updated plant-specific PRA would be available prior to fuel load for NRC audit and to support plant operations. Commenters suggested that the update of the plant-specific PRA during construction was a matter suitable to guidance.

Commenters expressed confusion over the NRC proposal to require PRA updates to reflect safety analyses and evaluations performed by the licensee, and analyses of new safety issues performed by or on behalf of the licensee at the NRC's request. The commenters stated that new analyses and evaluations were often performed using design basis assumptions that may not be appropriate for a PRA. Commenters suggested that only new analyses that impact the PRA warrant consideration, and requested guidance and examples be developed regarding the information that should be considered when updating the plant-specific PRA.

NRC Response: The NRC staff agrees with the basic intent of the industry comment regarding NRC Question 10, "New Requirements for Periodic Updates to the PRA," which is that the rule does not need to explicitly require combined license holders to submit to the NRC all changes to the PRA computer models (including fault trees and event trees, etc.) on a periodic basis. In DG-1145, the staff guidance does state that the COL applicant should describe their PRA maintenance and update program in Chapter 19 of their FSAR, but does not require the resubmittal of the PRA or submittal of changes to the PRA (i.e., submitting revised fault trees and event trees, etc.). It is expected that these PRA models will be maintained by the licensee to reasonably reflect the as-built, as-operated plant and will be available for NRC staff audit. In addition, the DG-1145 guidance also states that the licensee should periodically update FSAR Chapter 19 to describe plant and operational changes that have a significant impact on the PRA results and insights (as well as updating the description of the affected PRA results and insights).

Based on the above discussion and the regulatory guidance provided in DG-1145, the staff agrees with the industry that the proposed new requirement, identified in NRC Question 10, is not necessary.

4.11 Question 11: AP1000 - NEI-proposed changes for DCRs

Comment 007: Several commenters recommended the NRC incorporate the NEI recommendations on the AP 1000 rule, cited specific NEI recommendations (71 FR 12834-12836), and made additional suggestions and clarifications.

NRC Response: The NRC has reconsidered the comments from NEI on the AP1000 design certification rule (DCR) that were generic to all of the DCRs in appendices A - D of Part 52. The NRC's resolution of the generic DCR comments are set forth in the responses to question 11 in

Section IV of the Federal Register Notice. The additional comments on question 11 that were submitted by NEI are discussed below.

Comment 007-98: Regarding NEI recommendations (a) and (b), several commenters suggested it would be sufficient if the Statements of Considerations for the final rule provided the requested clarification, rather than the rule itself.

NRC Response: The NRC agrees with this comment and believes that the section-by-section analysis for the AP1000 DCR (71 FR at 4475) provides the necessary guidance on bracketed information in the generic technical specifications and the investment protection short-term availability controls.

Comment 007-99: Regarding NEI recommendation (f), several commenters supported the use of the term “include” rather than “physically include” for requirements in Section IV of the design certification rules concerning content of COLAs.

Commenters requested clarification on the permissible method of incorporating the generic DCD into the plant-specific DCD portion of the COL application’s final safety analysis report (FSAR), because the current NRC position has apparently “led to considerable confusion” among COL preparers. Commenters noted that in the Statements of Consideration accompanying the AP1000 final rule, NEI recommended a change to the Definitions (Section III.B of that rule, 71 FR 4466). Commenters stated the NRC staff disagreed with this recommendation, saying that “the generic DCD should also be part of the FSAR, not just incorporated by reference, in order to facilitate the NRC staff’s review of any departures or exemptions.” Commenters believed that this NRC position was in conflict with the current § 52.79(b), which states that the COL application’s FSAR “may incorporate by reference the final safety analysis report for a certified standard design,” and with § 50.32, which provides for incorporation by reference to eliminate repetitive information. Commenters argued that although the wording had been altered, the ability to incorporate by reference was preserved in proposed §§ 52.79 (b) and (c), respectively. Commenters claimed this interpretation of incorporation was validated by NRC staff during the DG-1145 workshops. The commenters stated support for this interpretation and requested the NRC explicitly describe that either approach is acceptable.

NRC Response: Regarding comment (f), the NRC agrees to use the term “include” rather than “physically include” and has modified Section IV of the DCRs. Commenters also requested clarification on the permissible method of incorporating the generic design control document (DCD) in the plant-specific DCD portion of the combined license (COL) application’s final safety analysis report (FSAR), because the NRC position has apparently “led to considerable confusion” among COL preparers. The NRC is requiring COL applicants that reference the DCRs in appendices A - D of Part 52 to include the generic DCD in the application’s FSAR, in order to facilitate the NRC staff’s review of any departures or exemptions. Simply incorporating the generic DCD by reference into the FSAR is not sufficient because of the manner in which these existing DCDs were submitted to the NRC. Therefore, Section IV.A.2 of the DCRs overrides §§ 50.32 and 52.79(d). The NRC is hopeful that future DCRs will not have to use this special requirement.

Comment 007-100: While discussing NEI recommendation (j), several commenters mentioned Section VIII.B.6.a of the design certification rules, which states that an applicant who references the design certification rule must obtain NRC approval for departures from Tier 2* information in the generic DCD. Commenters believed that this section states the departure is not considered to be a resolved issue under Section VI of the design certification rules. Commenters indicated this was inconsistent with Section VI.B.5 of the design certification rules, which states that license amendments are considered to be resolved. Commenters expressed support for the revision of Section VIII.B.6. of the design certification rules to make it consistent with Section VIII.B.5 of the design certification rules. Commenters stated that departures from Tier 2* information that are reviewed and approved by the NRC in the combined license proceeding should have finality for the plant in question.

NRC Response: The NRC does not agree with the request to modify Section VIII.B.6.a of the DCRs. The Commission decided during the initial design certification rulemakings that departures from Tier 2 information (by an applicant) would not receive finality or be treated as a resolved issue within the meaning of Section VI of the DCR. This provision applies to applicants for a combined license and the new information is subject to litigation in the same manner as other plant-specific issues in the licensing hearing. Also, Tier 2* information has the same safety significance as Tier 1 information and would have received the Tier 1 designation, except that NRC decided to provide more flexibility for this type of information.*

Comment 007-101: With respect to NEI recommendation (k), several commenters expressed concern that Section VIII.C.3 of the design certification rules “inappropriately” allowed the NRC to make changes to operational requirements in the DCD without satisfying the backfit requirements in § 50.109. Commenters stated that the operational requirements in the design certification proceeding should be afforded the protection of the backfit rule. Commenters supported a revision to Section VIII.C.3 of the design certification rules to include a reference to § 50.109 for these changes.

NRC Response: The NRC does not agree with NEI’s recommendation to modify Section VIII.C.3 of the DCRs. NEI wants the NRC to meet the backfit requirements in § 50.109 in addition to the special circumstances in § 2.335 in order to require plant-specific departures from operational requirements. In the original design certification rulemakings, the Commission decided on different standards for changes made under Section VIII.C (see Section VI.C and 62 FR at 25805; May 12, 1997). The Commission has decided that plant-specific departures should not have to meet the backfit requirements in § 50.109.

Comment 007-102: In the discussion of NEI recommendations (l) and (m), several commenters mentioned Section VIII.C.4 of the design certification rules, which states a COL applicant must request an exemption from the NRC if the applicant wants to depart from the generic technical specifications or other operational requirements. Commenters described this requirement as “unduly burdensome.” Commenters noted that the operational requirements do not have finality under Section VI.C of the design certification rules, and that no basis existed for applying such a change control process to a COL applicant seeking to change operational requirements. Commenters cited Section VIII.B.5 of the design certification rules, which states a COL applicant may depart from final design-related provisions in the design certification rule using a “50.59-like” process, and argued that imposing an exemption process with respect to operational provisions was not required. Commenters recommended Section VII.C.4 be

amended to state that a departure from an operational requirement does not require an exemption.

NRC Response: The NRC does not agree with NEI's recommendation to modify Section VIII.C.4 of the DCRs. The requirement in Section VIII.C.4 for an applicant to request an exemption applies to generic technical specifications and operational requirements that were comprehensively reviewed and finalized in the design certification rulemaking (see 62 FR at 25825; May 12, 1997). If the generic technical specifications were not reviewed, then there is no restriction on plant-specific changes to the technical specifications or other operational requirements and exemptions are not required. Because this guidance exists in the section-by-section discussion for the DCRs, the NRC has decided that changes are not necessary.

Comment 007-103: Several commenters mentioned information from NEI's September 30, 2003, response to the 2003 Part 52 Notice of Proposed Rulemaking. Commenters expressed support for the need to add a basic definition of "departure" to the DCRs to be consistent with adding the definition of "departure from a method of evaluation," and stated that both should be based on Regulatory Guide 1.187. Commenters stated, "The basic definition of 'change or departure' should precede the definition of departure from a method of evaluation." Commenters recommend adding the new definition as paragraph II.G and renaming the final two paragraphs as II.H and II.I.

NRC Response: The NRC does not agree with the recommendation to add a definition of "departure" to Section II of the DCRs. The NRC has provided an explanation of the term "departure" as used in the DCRs in Section V.C.4 of the Federal Register Notice.

4.12 Question 12: ITAAC Schedule - ITAAC required prior to fuel loading

Comment 007-105: Several commenters believed it was unnecessary to include a requirement for either the COL applicant or the COL holder to submit a detailed schedule for ITAAC completion because a COL applicant could provide only a progressively less accurate estimated completion schedule. Commenters stated that the COL holder would have schedules at the site, and those schedules would be available for NRC review. Commenters believed that COL holders would interact and coordinate with the NRC to ensure that NRC had sufficient information to schedule its inspection activities for ITAAC, making a regulatory requirement for submission of a schedule unnecessary. In addition, the commenters noted that a COL applicant/holder would likely consider detailed schedule information proprietary information, which would make its submission, in this case, inappropriate.

Several commenters also stated it was "wrong" to require completion of ITAAC in a set time period prior to fuel loading and operation. Commenters indicated that a COL holder would likely complete several ITAAC within 30 days of fuel loading and argued that the NRC should not abrogate responsibility by imposing a mandatory delay on licensees. Commenters stated the importance of the NRC providing the appropriate level of inspections and reviews to prevent delays in fuel load and emphasized the high cost (stated to be on the order of \$1,000,000 per day) of such delay. Commenters suggested the NRC should be in a position to make a § 52.103(g) finding promptly following the completion of the last ITAAC.

NRC Response: The NRC has decided to amend § 52.99 to require licensees to submit their detailed schedules for completing the inspections, tests, or analyses in the ITAAC. The NRC has added a new paragraph (a) in § 52.99 that requires licensees to submit to the NRC, no later than 1 year after issuance of the combined license, detailed schedules for completing the inspections, tests, or analyses in the ITAAC. Licensees are required to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, licensees must submit updates to the ITAAC schedule every 30 days until the final ITAAC is completed or until the final notification is provided to the NRC under § 52.99(c). Although commenters did not believe that a requirement for submission of a schedule was necessary, the NRC believes it is necessary to ensure that the NRC has sufficient information to plan all of the activities necessary for the NRC to support the Commission's determination as to whether all of the ITAAC have been met prior to initial operation. In the event that licensees consider their schedule information to be proprietary, they can request that the schedule be withheld from public disclosure under § 2.390.

The NRC is also revising § 52.99(c) by adding a new paragraph (c)(2) requiring that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by § 52.99(c)(1) for all ITAAC, then the licensee must notify the NRC that the inspections, tests, or analyses for all uncompleted ITAAC will be successfully completed and all acceptance criteria will be met prior to initial operation (consistent with the Section 185.b requirement that the Commission, "prior to operation," find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the inspections, tests, or analyses will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met. Paragraph (e) has been revised to require that the NRC make available to the public the notifications to be submitted under § 52.99(c)(1) and (c)(2), no later than the Federal Register notice of intended operation and opportunity for hearing on ITAAC under § 52.103(a). A conforming change is included in § 2.105(b)(3) to require that the § 52.103(a) notice reference the public availability of the § 52.99(c)(1) and (2) notifications. The NRC is requiring that the paragraph (c)(2) notification be made 225 days before the date scheduled for initial loading of fuel, in order to ensure that the licensee notifications are publicly available through the NRC document room and online through the NRC Website at the same time that the § 52.103(a) notice is published in the Federal Register. The NRC's goal is to publish that notice 210 days before the date scheduled for fuel loading, but in all cases the § 52.103(a) notice would be published no later than 180 days before scheduled fuel load, as required by Section 189.a(1)(B).

Commenters did not support addition of a requirement on completion of ITAAC in a set time period prior to fuel load and the NRC has not included a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date. Instead, the NRC has decided to modify the concept slightly by requiring the licensee to submit, with respect to ITAAC which have not yet been completed 180 days before the scheduled date for initial loading of fuel, additional information addressing whether those inspections, tests and analyses will be successfully completed and the acceptance criteria met before initial operation. In the case where the licensee has not completed all ITAAC by 180 days prior to its scheduled fuel load date, the NRC expects the information that the licensee submits related to uncompleted

ITAAC to be sufficiently detailed such that the NRC can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. In addition, the NRC is adopting the requirements in paragraphs (c)(1) and (c)(2) to ensure that interested persons will be able to meet the Atomic Energy Act, Section 189.a(1), threshold for requesting a hearing with respect to both completed and as-yet uncompleted ITAAC. The NRC therefore expects that the information submitted by licensees in the § 52.99(c)(2) notification will be sufficiently complete and detailed such that any licensee response to a contention on both completed and uncompleted ITAAC would ordinarily be answered solely by reference to information contained in the notification. Furthermore, the NRC expects that any contentions submitted by prospective intervenors regarding uncompleted ITAAC would focus on the inadequacies of the procedures and analytical methods described by the licensee for completing those ITAAC in the context of the reasonable assurance finding under § 52.103(b)(2). Therefore, the level of detail provided by the licensee should be sufficient to allow a prospective intervenor to form such judgments by reference to that information. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes “sufficient information” to demonstrate that the inspections, tests, or analyses for uncompleted ITAAC will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met.

The NRC notes that, even though it did not include a provision requiring the completion of all ITAAC by a certain time prior to the licensee’s scheduled fuel load date, the NRC staff will require some period of time to perform its review of the last ITAAC once the licensee submits its notification that the ITAAC has been successfully completed and the acceptance criteria met. In addition, the Commission itself will require some period of time to perform its review of the staff’s conclusions regarding all of the ITAAC and the staff’s recommendations regarding the Commission finding under § 52.103(g). Therefore, licensees should structure their construction schedules to take into account these time periods. The NRC staff intends to develop regulatory guidance on the licensee’s completion and NRC verification of ITAAC and will provide estimates of the time it expects to take to verify successful completion of various types of ITAAC. The NRC expects that such guidance, along with frequent communication with licensees during construction, will provide licensees with adequate information to plan initial fuel loading and related activities.

4.13 Question 13: ML Hearing - Provide opportunity for hearing by rule

Comments 007-106, 005-27(a), 005-22: Several commenters stated there was no need to require mandatory hearings for manufacturing licenses, or that the need for such hearings was unclear. Commenters expressed the belief that such hearings were not an appropriate method for reviewing and resolving technical issues. Commenters advised that the decision to request a hearing be left to either the NRC staff or stakeholders.

NRC Response: As stated in the statement of considerations for the March 13, 2006, proposed rule, the NRC acknowledges that hearings on initial issuances of manufacturing licenses are not required by the AEA (71 FR at 12814). The NRC also agrees with the general premise of the commenters that adjudicatory hearings may not be the best approach for resolving technical design issues - especially in uncontested proceedings. Indeed, the NRC removed the opportunity for adjudicatory-style hearings for design certifications as part of the 2004 changes

to 10 CFR Part 2 (January 14, 2004; 69 FR 2182). The primary responsibility for determining the safety of an application is with the NRC staff, and not the presiding officer. This is true regardless of whether the proceeding is contested or uncontested. Public confidence would not seem to be enhanced in any significant manner by the holding of a hearing where there is no request that the NRC hold a hearing. Accordingly, the NRC has decided not to adopt in the final Part 52 rule a requirement for a "mandatory" hearing in connection with issuance of manufacturing licenses.

4.14 Question 14: DCR Changes - Changes to design certification rules

Comments 006-2, 006-3, 006-4, 006-5, 007-9, 007-107, 009-3, and 016-2: Several commenters urged that current § 52.63 should be revised to allow the design certification applicant to obtain amendments to the design certification rule. The applicant should be able to petition the Commission for an amendment to incorporate "beneficial" changes to the design certification. Current NRC regulations appear to prevent any amendment to a design once the design has been certified by rule. Additional design work and other circumstances may result in a need for the applicant to make an amendment. Proposed changes should be permitted where they maintain both protection of the public health and safety and common defense and security. Such a process would result in worthwhile benefits in terms of improvements in safety, efficiency, and reliability relating to the design, construction, and operation of the plant. Amendments to the design certification rule to make beneficial changes should be permitted until the first COL referencing the design has been issued. If changes are needed after one or more nuclear power plants utilizing an approved standardized design are licensed and operating, then the amendments should only apply to plants that are not yet in operation.

NRC Response: The NRC has decided to include an amendment process for design certifications in the final rule that allows for: (1) generic resolutions of design acceptance criteria; (2) correction of errors; or (3) other changes that increase standardization, without meeting the special backfit requirement in the former § 52.63(a)(1). These amendments will apply to all plants that have referenced or will reference the DCR. The NRC believes that this process will enhance standardization by further completing or correcting the certification information and applying the amendment to all plants. A detailed discussion of the comments on this amendment process is provided in Section V.C.7.g of the supplementary information.

4.15 Question 15: Part 21 - Impose Part 21 reporting requirements on applicants during ESP and DC process

Comments 007-3 and 007-108: Several commenters were opposed to the proposed changes to Part 21. Commenters stated Part 21 had been in existence for almost 30 years, during which time it was never applied to applicants. They complained that they were not aware, and the NRC had not made them aware, of problems that would warrant a change. The commenters noted that applicants take measures to ensure that they were made aware of any errors and deficiencies identified by contractors and suppliers for work performed on commercial nuclear projects, because applicants eventually become holders, and licensees and want equipment to operate correctly. Several commenters were also concerned that the proposal was contrary to the Energy Reorganization Act (ERA), which was the basis for Part 21. They believed it would be inappropriate and contrary to the ERA to apply Part 21 to applicants. They stated Part 21 was established to implement Section 206 of the ERA, which

applies to “licensees” and vendors, suppliers, and contractors of licensees, not to “applicants.” The commenters cited 10 CFR 21.2, stating that the existing regulations of Part 21 apply only to entities licensed to possess, use, or transfer radioactive material within the United States, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or fuel storage facility. The commenters believed applicants did not fall within the scope of Section 206 of the ERA, and it was inconsistent with the Act to expand the scope of § 21.2 to include applicants.

Commenters also noted that it had been the standard practice for a construction permit (CP) applicant to specify Part 21 requirements in its procurement contracts for a plant prior to issuance of the construction permit. Commenters agreed with this practice because Part 21 was applicable to such contracts once the CP was issued by the NRC, and expected that this “good practice” would be implemented by COL applicants as well. From a “practical perspective,” the commenters believed this negated the need to expand Part 21 to applicants.

Commenters argued that the obligations for applicants to provide information to the NRC under proposed § 52.6(a) was broader than the obligation in Part 21, and would require applicants to update and correct their applications to account for the types of defects and noncompliances covered by Part 21. The commenters stated the industry had no objection to proposed § 52.6(a), which should therefore eliminate the need to apply Part 21 to applicants.

NRC Response: The Commission proposed Part 21 reporting requirements on applicants for early site permits, design certifications, and standard design approvals in the proposed rule. A detailed discussion on the Commission’s rationale for imposing these requirements in the final rule is provided in Section V.J of the Supplementary Information in the Federal Register notice.

5 Discussion of Substantive Changes and Response to Significant Comments

No comments received.

5.1 Introduction

No comments received.

5.2 Testing Requirements for Advanced Reactors

Comment 007-21: Several commenters noted that proposed 10 CFR§ 52.79(a)(24) and 50.43(e) would impose new testing requirements for COL applicants planning to build advanced designs that have not been certified. The commenters stated that the proposal conflicts with the Commission’s intent expressed in the original 1989 Statement of Considerations for Part 52 and may also present an undue burden and obstacle to commercialization of advanced designs.

The commenters explained that, in essence, proposed §§ 52.79(a)(24) and 50.43(e) would require that the same testing required of a design certification applicant be performed by a COL applicant that seeks a license for a non-evolutionary custom plant. The commenters noted that the proposed rule would require either (A) analysis, testing or experience, or (B) full-scale

prototype testing. The commenters also noted the Commission's statement that, for design certification of advanced reactors, it favors the use of a full-scale prototype in lieu of the other alternatives (51 FR 24643). The commenters believe it is unnecessary to apply these requirements to COL applicants, and that the potential requirement for a full-scale prototype testing is particularly inappropriate.

The commenters asserted that exercising the proposed COL requirement for prototype testing would create a logical disconnect. The commenters stated that absent a license, a prototype commercial nuclear plant cannot be built in the United States. The commenters noted that on the other hand, under the proposed rule, absent construction of a prototype, the design could not be licensed. The commenters stated that this "Catch-22" situation would effectively close an important path for bringing to market nuclear plant designs with innovative safety features. The commenters recommended that for these reasons, it would be inappropriate to establish or impose proposed § 50.43(e) (prototype testing) on COL applicant. In the alternative, the commenters suggested that the Statement of Considerations for the final rule should clearly state that the NRC does not prefer the use of prototypes over analysis, testing, or experience for licensing of reactors advanced reactors, and that the NRC may issue a COL for a prototype plant.

NRC Response: The NRC does not agree that the testing requirements for COL applicants conflict with the Commission's intent for Part 52 or that the requirements are unnecessary. When the Commission reformed the licensing process for new nuclear plants with the issuance of Part 52, it required applicants to demonstrate that the new safety features will perform as predicted in the final safety analysis report. Although the focus of the NRC at that time was on applications for design certification, the Commission intended that testing to qualify new design features (proof-of-performance testing) would be required for all advanced reactors, including custom designs (see Question 6 at 51 FR 24646; July 8, 1986). Furthermore, it would make no sense for the NRC to require qualification testing for design certification applicants (so-called paper designs) and not require testing for applications to build and operate an advanced nuclear power plant. Therefore, the NRC has implemented its intent in adopting Part 52 to resolve issues early and its policy on advanced reactors that it is necessary to demonstrate the performance of new or innovative safety features through design qualification testing for all advanced nuclear reactor designs or plants (including nuclear reactors manufactured under a manufacturing license).

The NRC also disagrees with the claim that the requirement for prototype testing would create a logical disconnect. The final rule provides an option in § 50.43(e)(2) for licensing a prototype plant, if the plant will be used to meet the testing requirements in § 50.43(e)(1). The new § 50.43(e) states that, if a prototype plant is used to comply with the qualification testing requirements, the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to compensate for any uncertainties associated with the performance of the new or innovative safety features in the prototype plant. Therefore, an applicant could request a COL for a prototype plant to meet the testing requirements.

Commenters stated that it would be inappropriate to establish or impose prototype testing on combined license applicants. Although the Commission stated that it favors the use of prototypical demonstration facilities and that prototype testing is likely to be required for certification of advanced non-light-water designs (see Advanced Reactor Policy Statement at 51 FR 24646; July 8, 1986, and 10 CFR Part 52 at 54 FR 15372; April 18, 1989), this rule does

not require the use of a prototype plant for qualification testing. Rather, this rule provides that if a prototype plant is used to qualify an advanced reactor design, then additional conditions may be required for the licensed prototype plant to compensate for any uncertainties with the unproven safety features.

The commenters stated that the fact that current § 52.79 does not reference the prototype testing requirements in § 52.47(b)(2)(i) was no mere oversight - it was intentional. The commenters noted that the Statement of Considerations for both the original proposed Part 52 (53 FR 32060, August 23, 1988) and the final Part 52 (54 FR 15372, April 18, 1989) indicate that design certification and licenses are to be treated differently with respect to prototype testing. The commenters cited several examples that the Commission wrote in those two rules. [See 53 FR 32063-64 and 54 FR 15374-75, 15383]

In addition, the commenters noted that the original 1986 Commission Policy Statement on Regulation of Advanced Nuclear Power Plants (51 FR 24643, July 8, 1986) indicated that the intent of the revised licensing process was to minimize complexity and uncertainty in the licensing process. The commenters stated that the addition of a prototype plant testing requirement minimizes neither the complexity nor the uncertainty, but rather adds to the uncertainty by inserting a significant additional step (currently representing an unknown quantity) prior to the licensing of a plant of a new design.

NRC Response: The commenters have misinterpreted the Commission's requirements and policy on prototype plants. The Commission's policy on the licensing processes in Part 52 is to provide alternatives to the licensing process in Part 50. As stated above, the requirement in § 50.43 provides an option for licensing a prototype plant to perform testing of safety features.

The commenters noted that the Commission has stated that prototype testing will likely be required for design certification of advanced reactors. However, the commenters stated that there are significant differences between certified and custom designs. The commenters noted that a certified design is effective for 15 years, may be incorporated by reference by any license applicant without further review and approval by the NRC, and is subject to broad protection against backfits under the change control process in 10 CFR 52.63.

The commenters noted that in contrast, the arguments for prototype testing for certification of advanced reactors do not apply to licensing of advanced reactors. The commenters asserted that unlike a design certification, licensing represents approval of only a single facility. The commenters stated that licensing of subsequent facilities, even if identical in design, is still subject to NRC review and approval including possible design changes to account for any unfavorable results of startup and power ascension testing and operating experience from previously licensed facilities. The commenters further stated that, unlike a design certification, the NRC has fairly broad authority under 10 CFR 50.109, "Backfitting," to impose backfits on a licensed facility to account for any unfavorable results of startup and power ascension testing and operating experience. The commenters stated that finally, in lieu of prototype testing, the NRC has authority to impose special license conditions that might not be necessary or appropriate if applied to all plants with a standard design (e.g., a license condition can require special design, procedural, or testing provisions to provide adequate protection of safety until the design is demonstrated to be safe through testing or operation). The commenters recommended that because of these arguments, there is no compelling reason for a full-scale prototype test facility prior to licensing of an advanced reactor.

NRC Response: Once again, commenters have misinterpreted the Commission's requirements and policy on prototype plants. As stated above, the final rule does not require the use of a prototype plant for qualification testing. Rather, this rule provides that if a prototype plant is used to qualify an advanced reactor design, then additional conditions may be required for the licensed prototype plant to compensate for any uncertainties with the unproven safety features.

The commenters stated that it is simply unnecessary to impose on COL applicants the requirements of § 50.43(e) to demonstrate safety features via analysis, testing, and/or experience. The commenters stated that this is because the COL applicant is already subject to 10 CFR 50.34(b)(4) requirements to provide sufficient information of this type to support the required NRC safety determination on the design. The commenters also stated that in addition, at COL issuance, the NRC has authority to establish license conditions, including conditions on successful demonstration of unique design features.

The commenters noted that NRC guidance and past precedent indicate that a full-scale prototype testing facility need not precede licensing of a new type of reactor. The commenters noted as an example that NRC Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - LWR Edition," which provides the standard format and content for safety analysis reports, explicitly states that special, unique, or first of a kind design features may be verified through startup test. [See NRC Regulatory Guide 1.70, Section 14.1.2.]

Similarly, the commenters noted that NUREG-0800, "Standard Review Plan" Section 14.2, Paragraph III.8, recognizes that the initial test program in FSARs may include provisions for "testing for special, unique, or first-of-a-kind design features." The commenters stated that therefore, NRC guidance clearly allows for testing of unique and first-of-a-kind design features through the startup and power ascension test program, and does not require prototype testing prior to issuance of a license for a plant involving such features. The commenters concluded that through its existing requirements and regulatory authority, the NRC may assure that applicants provide adequate information to support required COL reviews and safety determinations, as well as satisfactory demonstration of innovative design features during startup and power ascension testing.

NRC Response: As stated above, commenters continue to misinterpret the Commission's requirements for demonstration of new safety features. The requirements in § 50.43 for demonstration testing are unrelated to the requirements for safety analyses in § 50.34(b)(4). However, the NRC agrees that the COL for a prototype plant will contain conditions on the successful demonstration of new design features. Also, regarding the references to NRC Regulatory Guide 1.70 and NUREG-0800, Section 14.2, commenters have confused verification testing for approved design features with the testing that is necessary to demonstrate new design features.

5.3 Changes to 10 CFR Part 52 (Subparts A - H)

Referencing ESPs and Design Certifications in COL Applications

Comment 005-1: A commenter suggested that the NRC's discussion of the regulatory changes (page 12786 of the Federal Register notice) focuses narrowly on the idealized process

envisioned when Part 52 was originally developed: a combined license (COL) application that references previously completed early site permit (ESP) and design certification (DC) proceedings. The commenter believes that this approach ignores the fact that none of the COL applications (COLAs) that have been announced for submission to the NRC in the 2007-2008 time frame will reference both an already-certified design and an ESP. The commenter pointed out that those COLAs that will reference a DC do not involve ESPs, while those that will reference completed ESPs will not reference a design for which certification is complete. The commenter suggested that lack of consideration of the actual types of cases with which the NRC will be presented results in regulatory requirements that are, in some cases, not well-suited for use by potential COL applicants whose approach varies from the one stated above. The commenter encouraged the NRC to focus on developing rules that are equitable and clearly applicable for all potential COL applicants.

NRC Response: The Commission disagrees with both the commenter's observation that the SOC's discussion of the regulatory changes focuses on the "idealized process" of a combined license referencing both an early site permit and a standard design certification, as well as the commenter's suggestion that the NRC failed to consider the actual types of cases for which the NRC will be presented. A fair reading of the both the SOC and the provisions of the proposed rule demonstrates that no particular course of action is favored or encouraged; Part 52 is structured to provide the combined license applicant many different alternatives. The Commission also finds it presumptuous of this commenter to suggest that the it knows what "actual types" of applications will be submitted to the NRC in the future. While current prospective applicants may decide to utilize a particular approach for pursuing a combined license application because of their own circumstances and business imperatives, the Commission cannot bias its regulations in such a manner unless the Commission believes that there are sound regulatory reasons for doing so. The commenter presented no information that constitutes such regulatory basis.

Comment 007-8: Several commenters noted that § 52.55(c) allows a construction permit or COL applicant, at its own risk, to "reference in its application a design for which a design certification application has been docketed but not granted." Several NRC licensees and/or consortia are considering filing COL applications that reference a DC application. Because Part 52 currently does not specify the procedures to be followed in such a situation, further direction from the NRC is now needed as to how § 52.55(c) should be implemented. Specifically, the commenters recommended that the NRC revise § 52.55(c) to provide clarification and direction on handling COL applications that reference DC applications. Such guidance is needed to enhance the efficiency of both the NRC staff's review and the conduct of NRC hearings on COL applications that reference a DC application. Industry's goal in this regard is to preclude the NRC staff and the NRC Atomic Safety and Licensing Board from conducting duplicative review of DC application issues in the COL proceeding pending issuance of the final DC. Such redundant licensing reviews and/or redundant litigation of DC standard design issues in connection with a COL application will almost certainly delay and further encumber the Part 52 licensing process, with no attendant increase in the protection of public health and safety or the environment. Such redundant reviews would pose the potential for inconsistent results in the multiple proceedings, and possibly the loss of standardization.

NRC Response: The Commission does not agree with the commenters that rulemaking changes should be adopted to specify in detail the review procedures and hearing matters to be

utilized when a combined license application references either an proposed (rather than final) standard design certification rule, or a early site permit application, or both. The Commission believes that codifying a specific approach for conducting such a proceeding, which is not likely to be used extensively by applicants, for which there is no Commission experience, and for which the Commission did not request stakeholder input on, would not be prudent. The Commission believes that existing law and the inherent flexibility afforded by Part 52 and Part 2, may the basis for issuance of generic guidance or case-specific Commission action addressing this matter. For these reasons, the Commission declines to adopt the commenters' proposal, and no change to any part of the final rule has been made as the result of the comments.

Comments 007-8, 013-8: Several commenters noted that 10 CFR 52.27(c) allows a construction permit or COL applicant, at its own risk, to “reference in its application a site for which an early site permit application has been docketed but not granted.” The commenters continued to note that § 52.55(c) allows a construction permit or COL applicant, at its own risk, to “reference in its application a design for which a design certification application has been docketed but not granted.” The commenters stated that beyond this permissive language, the regulations provide no further detail and that the current proposed amendments to 10 CFR Part 52 do not propose changes to §§ 52.27(c) or 52.55(c). [See 71 FR 12892, 12897.]

The commenters stated that, consistent with existing §§ 52.27(c) and 52.55(c), several NRC licensees and/or consortia are considering filing COL applications that reference an ESP application or a DC application. The commenters stated that because 10 CFR Part 52 currently does not specify the procedures to be followed in such a situation, further direction from the NRC is now needed as to how §§ 52.27(c) and 52.55(c) should be implemented. This topic (under the heading of the need for “licensing flexibility” in the new 10 CFR Part 52), was specifically mentioned in NEI’s December 14, 2005, letter to NRC Chairman Diaz responding to questions and comments raised in the November 21, 2005, NRC-industry meeting. The commenters went on to state that one advantage of addressing this issue in the ongoing Part 52 rulemaking is that the NRC could thereby provide a clear, definitive, and generic regulatory solution to this question. Further, the commenters believe that the promulgation of a more detailed process in 10 CFR§ 52.27(c) and 52.55(c) would be consistent with the Commission’s recent directive to the NRC staff to include in the Part 52 rulemaking “proposed strategies for staff review of expected applications and support for COL hearings before the Atomic Safety and Licensing Board Panel.” [See Jan. 30, 2006 Staff Requirements Memorandum re SECY-05-0203 from the Commission, p. 3.]

Specifically, the commenters recommended that the NRC revise 10 CFR§ 52.27(c) and 52.55(c) to provide clarification and direction on handling COL applications that reference ESP or DC applications. The commenters stated that such guidance is needed to enhance the efficiency of both the NRC staff’s review and the conduct of NRC hearings on COL applications that reference an ESP or DC application. The commenters noted that Industry’s goal in this regard is to preclude the NRC staff and the NRC Atomic Safety and Licensing Board (Licensing Board) from conducting duplicative reviews of DC and ESP application issues in the COL proceeding pending issuance of the final DC and ESP. The commenters stated that such redundant licensing reviews and/or redundant litigation of ESP siting issues and DC standard design issues in connection with a COL application will almost certainly delay and further encumber the Part 52 licensing process, with no attendant increase in the protection of public health and safety or the environment. The commenters stated that redundant licensing reviews

for new plants are also inconsistent with the Commission's stated goal, in the current rulemaking, to "more effectively and efficiently implement the licensing and approval processes for future nuclear power plants under Part 52." [See 71 FR 12783.] The commenters continued to state that such redundant reviews would pose the potential for inconsistent results in the multiple proceedings, and possibly the loss of standardization.

In particular, the commenters proposed that the text of §§ 52.27(c) and 52.55(c), and/or the discussion on the Statements of Consideration accompanying the NRC final rule, make the following points: (1) the hearing for a COL application may proceed pending issuance of the ESP or DC referenced in the COL application, provided that a docketed ESP or DC application precedes the docketed acceptance date of the COL application; (2) the issues that will be addressed in the referenced ESP proceeding or the DC proceeding/rulemaking may not be addressed in the COL application hearing, and may not form the basis for admissible contentions in the COL proceeding, except as may be combined in a single license proceeding under § 52.8, and that the Licensing Board presiding in the COL hearing would defer consideration of matters to be resolved in the ESP or DC proceeding, including any contentions adjudicated in those proceedings; however, litigation on other COL issues would proceed; (3) the COL application hearing should be based upon the information contained in the DC application and/or ESP application, as amended at the time of COL application hearing commences, and if the DC application or ESP application were to change after the conclusion of the COL application hearing, additional hearings may be necessary if those changes impact the issues considered in the COL proceeding; (4) that upon issuance of the ESP or DC, the COL applicant would amend the COL application to reference and conform to the final ESP or DC; (5) the commencement of a COL hearing for a COL referencing a pending ESP or DC application would be at the risk of the COL applicant, consistent with existing §§ 52.27(c) and 52.55(c).

The commenters stated that underlying this proposed regulatory approach is the assumption that a COL application referencing an ESP or DC application should be treated similarly to a COL application that references a final ESP or DC. [See 10 CFR 52.73] The commenters stated that in terms of the licensing review, they propose that the NRC staff and the Advisory Committee on Reactor Safeguards (ACRS) would review siting issues in the context of the ESP proceeding and standard design issues in the context of the DC proceeding. The commenters stated that in the COL proceeding, the staff and the ACRS would subsequently rely upon these previous reviews and treat siting matters and standard design matters as final, thereby avoiding duplicative reviews of siting and/or design issues in the COL proceeding.

The commenters suggested that, regarding the interface between the COL proceeding and the ESP or DC application, the NRC staff and ACRS would assume that the information in the ESP or DC application is final. If the referenced ESP or DC application is later amended, the staff and ACRS would account for that amendment in their review of the COL application, and the applicant would amend the COL application as needed.

In addition to revising the text of the affected regulations in either Part 2 or Part 52, the commenters asked that the NRC staff include explanatory language addressing these concepts in the Statements of Consideration accompanying issuance of the final rule amending 10 CFR Part 52, to provide maximum clarity on these points.

NRC Response: The Commission does not agree with the commenters that rulemaking changes should be adopted to specify in detail the review procedures and hearing matters to be utilized when a combined license application references either an proposed (rather than final) standard design certification rule, or early site permit, or both. The Commission believes that codifying a specific approach for conducting such a proceeding, which is not likely to be used extensively by applicants, for which there is no Commission experience, and for which the Commission did not request stakeholder input on, would not be prudent. The Commission believes that existing law and the inherent flexibility afforded by Part 52 and Part 2, may be the basis for issuance of generic guidance or case-specific Commission action addressing this matter. For these reasons, the Commission declines to adopt the commenters' proposal, and no change to any part of the final rule has been made as the result of the comments.

Retroactivity of Proposed New Requirements on Existing and Pending ESP and Design Certifications at the Time of Adoption of the Final Rule

Comments 006-7, 007-7, 012-10: Several commenters noted that the Proposed Rule contains more than thirty new requirements on applicants for ESPs and design certifications. However, the commenters noted that the Proposed Rule is silent on whether the proposed new requirements would be imposed on applications for ESPs pending and/or on ESPs which already have been issued at the time of adoption of a final rule. The commenters noted that the Proposed Rule is also silent on whether the proposed new requirements would be imposed on designs which already have been certified, on applicants for those certified designs, and/or on applicants for designs which have not yet been certified at the time of issuance of a final rule.

The commenters also noted that the proposed rule is silent on whether, in the COL licensing process, the new requirements could be raised and imposed on a COL license applicant who references an ESP or a certified design. The commenters stated that this would reopen, via the "back door," the ESP or the certified design. The commenters clarified that the Proposed Rule leaves open the question of whether an ESP or standardized design that is referenced in the COL licensing process (including any licensing hearing) will be subject to reopening because of the adoption by the Commission of the new requirements in the Proposed Rule.

The commenters went on to state that possible retroactive application of the proposed new requirements on existing ESPs or certified designs, or on pending applications for ESPs or design certifications at the time of adoption of the final rule, "introduces new, substantial uncertainty into the Part 52 process and is very troubling." The commenters believe that to apply the new regulations retroactively "would frustrate the idea of finality, which is a cornerstone of Part 52." The commenters noted that for the Commission to have certified a design, the Commission must have been satisfied that relevant Commission regulations were met. The commenters stated that it must be inherent in the certification of a design that no alternative or additional features are required for the design and that all safety issues associated with the design have been satisfied. The commenters continued that similarly, for the Commission to have issued an ESP, they must have been satisfied that applicable Commission regulations were met.

The commenters noted that a representative of their group raised the question of no retroactivity of the Proposed Rule in the NRC Stakeholders Meeting to Discuss Proposed Rule

Change 10 CFR Part 52 (Transcript, p. 15 1). The commenters noted that the NRC representative responded affirmatively to this assumption (Transcript, pp. 151 - 152):

One of the commenters also stated that, as a general matter, no change should be made retroactive if it would affect or delay a current proceeding. The commenter noted that the proposed changes include provisions that might affect the form or contents of ESP applications, as well as the staff's safety analysis report and EIS. The commenter noted as an example that proposed § 52.17(a)(1)(x) would add a new requirement to evaluate the potential hazards of construction activities on existing units, which is a requirement that is currently inapplicable to an ESP application. The commenter also noted that other new requirements would be imposed by proposed §§ 52.17(a)(1)(xii) - (xiii), 52.17(c), and 52.24(a)(4). The commenter stated that if it were necessary to revise pending applications and NRC staff review documents as a result of such changes, the current proceedings could be delayed considerably. The commenter asserted that this would penalize the companies that have undertaken to demonstrate the new licensing process.

Thus, the commenters support the NEI position that any final rule adopted by the Commission should include a "grandfather" clause to exempt ESPs and certified designs that are in existence, and applications for ESPs and certified designs that are pending, on the effective date of any new requirements. The commenters stated that any new requirements promulgated by the Commission should not apply to ESPs that have been issued or standard designs that have been certified prior to promulgation of the new requirements; and any new requirements should only apply to ESP applications and certified design applications filed after the effective date of the new regulations.

NRC Response: The Commission does not agree with commenters suggesting that a grandfather clause is needed for existing design certifications. The four standard design certifications already issued are not be subject to new technical requirements as the result of the final Part 52 rule because any technical changes in Part 50 or elsewhere in Title 10 of the CFR." Moreover, changes in Part 52 which apply to the content of applications or the process and criteria for consideration of design certification applications are not applicable to already-issued design certification rules. Finally, an all-inclusive grandfathering clause would exclude the existing design certification rules from the several burden reduction and regulatory improvement changes included in the final rule, such as the expanded scope of changes which can be made to design certification rules under § 52.63(a)(1).

The Commission also does not agree with commenters that the final rule's technical provisions should not be applied to applications for standard design certifications that have not yet been adopted by the Commission at the time of the issuance of this final rule. The Commission's longstanding requirement in Part 52 is that design certifications must meet the Commission's requirements in effect at the time of issuance of the final design certification rule. The Commission's practice in implementing this regulatory requirement is a two-part process of: (i) including an exemption from the new requirement in the final design certification rule, and (ii) establishing an "applicable regulation" in the final design certification rule that function in lieu of the exempted regulation. See Section V., "Applicable Regulations," in Appendices A-D of Part 52. This approach was developed by the NRC with public comment from various stakeholders, including each of the applicants for the design certification and NEI. The commenters provided no basis for departing from this past practice.

The Commission also disagrees with commenters that the early site permit applicants currently under consideration by the NRC, should not have to meet any applicable new requirements in the final rule. Former § 52.24 - by failing to specify a “cut-off date” for the applicability of Commission requirements - requires that early site permits meet the regulations in effect and applicable at the time of issuance of the early site permit. This is also true for design certifications under Part 52, as well as construction permits under Part 50. The Backfit Rule, 10 CFR 50.103, is consistent with this interpretation inasmuch as backfitting protections come into effect only upon issuance of the construction permit, see § 50.103(a)(1)(I). As a practical matter, virtually all of the provisions in the March 2006 proposed rule were applied to the current early site permit applicants in the review process. Therefore, there should be little impact on these applicants, and likely to be no need for the NRC to grant exemptions from the final Part 52 rule when issuing the ESPs to these applicants.

The Commission does not believe that a combined license applicant referencing either an early site permit or standard design certification rule could be required to meet new requirements within the scope of the early site permit or design certification, except as provided in relevant the finality provisions, §§ 52.39 and 52.63. Furthermore, the Commission has added a new regulatory provision, § 52.98, governing finality in Subpart C governing combined licenses, which reinforces the finality provisions in §§ 52.39 and 52.63. None of the commenters addressed why these regulatory provisions are insufficient to provide the necessary level of regulatory stability. Furthermore, one commenter’s (NEI) proposed rule language (NEI Comment, p. 15) establishes change restrictions for design certifications which is not only inconsistent with the pre-existing change restrictions in Part 52, but also is entirely inconsistent with that commenter’s separate proposal (NEI Comment, p. 20) to expand the scope of changes that may be made to design certifications.

In sum, the rulemaking provisions cited above, together with this comment response, provides future combined license applicants with regulatory stability and predictability in this area. Accordingly, for the reasons discussed above, the Commission has not included a “grandfather clause” in the final rule.

PRA Requirements Throughout Part 52

Comment 007-1: Several commenters stated that the proposed rule does not justify the requirements listed in proposed §§ 52.47(b)(1), 52.80(a), 52.137(b)(1), and 52.158(a), which would require applicants to submit a probabilistic risk assessment (PRA) as part of their applications.

The commenter suggested that applicants should not be required to submit their complete design-specific or plant-specific PRA. Instead applicants should only be required to provide a summary description of results, insights, and methodologies of their PRA in their final safety analysis report (FSAR). The complete PRA (e.g., codes) would be available for NRC inspection at the applicant’s offices.

The commenters also stated that they understand that it is not the NRC’s intent to require submission of the complete PRA based on discussions with the NRC staff during a March 14, 2006, workshop (Tr. 115-116). The commenters noted that Section 4.4 of draft NEI 04-01, *Industry Guideline for Combined License (COL) Applicants Under Part 52, Revision E* (October

2005), states that the design PRA for the referenced standard design is expected to serve as the plant-specific PRA to support a COL application. Chapter 19 of COL FSARs will provide information that demonstrates that a referenced design certification PRA bounds site- and plant-specific information, including an evaluation of unbounded site- and plant-specific information to determine that any differences have no significant impact on design PRA insights/results/methodologies. The commenters stated that re-submittal of extensive design PRA information (e.g., logic models, etc.) or the complete PRA as part of the COLA is not necessary as this information was reviewed and approved in connection with the design certification.

The commenters suggested that updated, plant-specific PRA analyses should be developed to support a COLA (1) if necessary to reflect and assess significant differences between plant-specific information and that assumed in the design PRA, (2) if needed to support a risk-informed departure or exemption from the design certification or other NRC requirement, or (3) if needed to support risk-informed design or operational requirements (e.g., 10 CFR 50.69 or NFPA-805). The commenters noted that maintaining such updated plant-specific PRA analyses available for NRC inspection (i.e., COL applicants would not need to submit this information with their COL applications) would be consistent with current practice for design certification and for operating plants.

The commenters noted that the plant-specific PRA that supports the COL application would be updated as plant-specific design and as-built information is developed during construction. This update will be consistent with PRA scope and quality standards in effect six months before the COL is issued. In this way, an updated plant-specific PRA that is representative of the as-built plant will be completed and available prior to fuel load to support plant operations.

The commenters noted that in addition, proposed § 52.80(a) would require a COL applicant that references a design certification, standard design, or manufacturing license to update the referenced PRA to account for “any design changes, departures, or variances.” The commenters stated that this provision could be misconstrued as requiring the updated PRA to address all design changes, including changes that are not relevant to the PRA. The commenters understand that the NRC agrees that the intent of this provision is only to require the updated PRA to account for design changes that are relevant to the PRA.

The commenters suggested that the FSAR Chapter 19 summary description of the PRA would satisfy the above § 52.80(a) requirement for COLA. The commenters expect that guidance regarding the Chapter 19 PRA summary description will be developed as part of the guidance in DG-1145, COL Applications for Nuclear Power Plants (LWR Edition), currently under development by the NRC staff.

NRC Response: The NRC agrees that applicants should not be required to submit their complete design-specific or plant-specific PRA and that, instead, applicants should only be required to provide a summary description of the PRA and its results (PRA information) in their final safety analysis report (FSAR) with the understanding that the complete PRA (e.g., codes) would be available for NRC inspection at the applicant's offices. The NRC has modified the final rule in several places to reflect this understanding, namely in §§ 52.47, 52.79, 52.80, 52.137, 52.157, and 52.158. The NRC expects that final rule §§ 52.79(a)(38) and 52.79(a)(46) will be addressed in a COL applicant's FSAR, Chapter 19. Consistent with Commission direction in the SRM on SECY-05-0203 (ML060300640), the details regarding scope and

methods acceptable to meet these requirements are to be addressed in regulatory guidance. Draft regulatory guide DG-1145 provides specific guidance for what a COL applicant should include in its FSAR, including Chapter 19 that addresses the applicant's plant-specific PRA and severe accident evaluations. The staff believes that the guidance provided in DG-1145 for the contents of Chapter 19 is consistent with the industry comment in that the staff does not expect the complete PRA to be included in the COL applicant's FSAR. Instead, the guidance is oriented towards the qualitative description of the PRA and its results, etc. In the case where a COL application is referencing a design certification, the NRC only expects the design changes and differences in the modeling (or its uses) pertinent to the PRA information to be addressed to meet the submittal requirement of § 52.79(d)(1). For COL applicants that do not reference a certified design, it will be necessary for the applicant to provide plant-specific PRA information for the entire plant.

New Requirements for Severe Accident Information

Comments 005-8 and 007-2(a): Proposed §§ 52.47(a)(20), 52.79(a)(38), 52.137(a)(20) and 52.157(j) would require applications for design certification, COLs, design approvals and manufacturing licenses to include a description and analysis of design features for the prevention and mitigation of severe accidents (core-melt accidents), including challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen detonation, and containment bypass. The commenters stated that the Supplementary Information for the proposed rule does not explain the basis for this proposed change, nor does it justify the change. Commenters believe that the proposed new requirement is inappropriate and unwarranted, and that NRC's existing guidance adequately addresses the need to discuss severe accident features in applications for new nuclear plants. The existing design certifications, which include a description and analysis of severe accident mitigation features as appropriate, provide ample evidence of this. The commenters stated that there is no reason to elevate existing guidance to the status of a regulation.

The commenters also stated that the proposal introduces severe accident design information requirements "in a manner that implies 'incorrectly' that severe accidents are part of the design bases, as defined in 10 CFR 50.2." Commenters stated that there is no explanation or basis provided for treating severe accident design requirements as part of the plant's § 50.2 design basis and that, in particular, it would be inappropriate to apply all of the typical design basis accident requirements (e.g., single failure requirements, quality assurance requirements, environmental qualification requirements) to severe accidents. The commenters understand that it is not the NRC's intent to require plants to apply design basis requirements to severe accident features. At the very least, commenters suggested that the proposed rule should be clarified to indicate that an applicant need not apply design basis requirements to severe accident features or analyses.

NRC Response: The Commission does not agree with the comment. First of all, the requirements for severe accident design information for future plants are not new and have been in place since issuance of the Commission's SRMs on SECY-90-016 and SECY-93-087. These requirements are included in the contents of applications for design certifications, combined licenses, design approvals, and manufacturing licenses for completeness and accuracy. Also, as noted by the commenter, the information was provided in previous design

certification applications. The inclusion of this requirement is consistent with the overall philosophy of this rulemaking, which is to clarify the licensing processes in 10 CFR Part 52.

Second, the commenter incorrectly asserts that design basis information, as defined in 10 CFR 50.2, must meet design basis accident (DBA) requirements, e.g., single failure, quality assurance, and environmental qualification. This assertion is clearly wrong and there is a lot of design information in a final safety analysis report (FSAR) that constitutes part of the plant's design basis but is not required to meet DBA requirements, e.g., the severe accident design features do not have to meet DBA requirements, as stated in SECY-90-016 and SECY-93-087. This clarification will be described in the section-by-section discussion. However, the severe accident design features must be described in the FSAR and will be part of the plant's design basis consistent with the definition in § 50.2 and past practice.

Comment 007-2(b): A commenter stated that even if these proposed requirements were not construed to be design bases requirements, severe accident requirements should not be imposed as broad generic requirements without extensive interactions with stakeholders to determine the ramifications and propriety of doing so. For example, the commenter noted that the proposed severe accident requirements are not appropriate for all reactor types. In particular, the commenter stated that such requirements should not be imposed upon gas cooled reactors, which are not susceptible to events such as steam explosions, high-pressure core melt ejection, and hydrogen detonation. Therefore, at the very least, the commenter suggested that the proposed provision should be modified to limit its applicability to light water reactors.

NRC Response: The Commission agrees that the requirements in its SRMs on SECY-90-016 and SECY-93-087 were developed for light-water reactor designs. Therefore, the requirement for providing a description and analysis of the design features in the contents of applications will be limited to light-water reactor designs.

Comment 007-2(c): A commenter noted that the proposed rule states that the application must provide a description and analysis of design features to "prevent" severe accidents. However, the focus of the proposed provision and all of the examples listed pertain to mitigation of severe accidents. Moreover, the commenter stated that the set of design features to "prevent" severe accidents is unbounded in the sense that the bulk of SSCs in a nuclear plant are designed to assure safe operation and prevent severe accidents. Therefore, the commenter suggested that the proposed rule should be modified to delete any reference to prevention of severe accidents.

Comment 005-9: The commenter stated that although the term "severe accident" is used in various places in the revisions to Part 51 and Part 52, the term is not defined in either of these rules, nor in Section 11 of the AEA. If the term is going to be used, the commenter stated that it should be clearly defined so there is no question about what constitutes a "severe accident." The commenter said that NRC should review the Commission's Severe Accident Policy Statement to ensure its definition of "severe accident" is consistent with past usage of the term.

NRC Response: The NRC recognizes that the term "severe accident" is used in many places throughout the regulations in Parts 51 and 52. However, the term is not consistently used in all of these requirements. Therefore, the reader needs to review the supplementary information in

the Federal Register Notice and other guidance documents for the specific explanation. An example is the severe accident change process in Section VIII.B.5.c of the design certification rules in Part 52. The supplementary information for these rules defines severe accidents for the purposes of that requirement.

New Requirements for Evaluation of Operating Experience

Comment 007-12: Several commenters noted that proposed 10 CFR§ 52.47(a)(19), 52.79(a)(37), 52.137(a)(19), and 52.157(p) would impose new requirements for applicants for a design certification, COL, manufacturing license, or standard design approval to address generic letters and bulletins issued up to six months before the docket date of the application, and comparable international operating experience. The commenters stated that the Supplementary Information for the proposed rule provides no justification for including a requirement to provide information on operating experience in Part 52 applications and that, in addition, no guidance is provided regarding the threshold or mechanism for consideration of operating experience. The commenters recommended that the NRC delete these proposed provisions.

The commenters noted that the Notice of Proposed Rulemaking (NPR) does reference the Staff Requirements Memorandum (SRM) dated February 15, 1991, as a basis for this proposed requirement. However the SRM simply states that applications should “incorporate the experience from operating events in current designs which we want to prevent in the future.” It does not require an evaluation of every NRC generic letter and bulletin, let alone international experience. The commenters stated that this is unnecessary because operating experience is reflected in other regulatory guidance that applicants are required to consider.

The commenters stated that the proposed requirement to address “comparable international experience” is vague, undefined, and unbounded, and that such a requirement could prove especially problematic in licensing hearings, since it could result in an applicant being forced to consider relatively trivial events identified by intervenors. Additionally, the commenters noted that to the extent that international experience is significant, presumably the NRC would take actions to communicate that experience in a generic letter or bulletin. See, e.g., NRC Generic Letter 97-01, “Degradation of Control Rod Drive Mechanism Nozzle and Other Vessel Closure Head Penetrations,” which discusses international experience with cracking in Alloy 600 vessel head penetrations.

NRC Response: The NRC disagrees with this comment. First of all, the NRC’s requirement to address operating experience insights is not new. This requirement was developed for future plants (see SRM on SECY-90-377 dated February 15, 1991) and it has been implemented in past design certification reviews by addressing NRC’s generic letters and bulletins. This past experience provides the necessary guidance for future applicants. Second, the NRC agrees that insights from generic letters and bulletins should be incorporated into the latest revision of the standard review plan and has revised this requirement accordingly. Finally, regarding the requirement to address comparable international operating experience, the NRC understands that some future applications may be for designs that are not based on or are not evolutions of plants that are operating in the United States. The NRC’s generic letters and bulletins may not provide operational insights for those non-U.S. designs. Therefore, the NRC expects those

applications to address how insights from any relevant international operating experience have been incorporated into their plant design.

The commenters stated that even without the requirement to address “comparable international experience,” the proposed requirements are unnecessary and unduly burdensome. The commenters noted that the NRC’s regulations already require an applicant to address the Standard Review Plan (SRP) in effect six months prior to submission of the application. The NRC is currently engaged in an extensive effort to revise and update the SRP, and the commenters understand and expect that update will include lessons learned from operating experience to the extent appropriate. Furthermore, the commenters stated that § 52.47 already requires design certification applicants to address unresolved safety issues and high and medium priority generic safety issues in NUREG-0933, and proposed § 52.79(a)(20) would require COL applicants to do the same. In sum, the commenters stated that the intent of the proposed new requirements to ensure consideration of operating experience, as appropriate, is already achieved by other proposed and existing NRC requirements.

NRC Response: The NRC does not agree that this requirement is unnecessary and unduly burdensome. Furthermore, unresolved safety issues and generic safety issues may not address all of the operational insights. However, as stated above, the NRC does agree that insights from generic letters and bulletins should be incorporated into the latest revision of the standard review plan and has revised this requirement accordingly.

The commenters also stated that the requirement to address all generic letters and bulletins is unduly burdensome. For example, the NRC has been issuing generic letters and bulletins since the 1970s. The commenters noted that in some cases, those generic letters and bulletins have been superseded by later generic letters and bulletins, other NRC guidance, or NRC regulations. The commenters stated that requiring applicants to address issues that are thirty years old and in some cases have been superseded by intervening developments is not a wise use of NRC or industry resources. Therefore, to the extent that NRC decides to retain a requirement to consider generic letters and bulletins, the commenters suggested that the requirement should be limited in time (e.g., to those generic letters and bulletins issued since the most recent revision of the applicable SRP sections).

NRC Response: The NRC agrees with this comment and, as stated above, has revised this requirement so that applicants only need to address operating experience insights from generic letters and bulletins issued after the most recent revision of the applicable standard review plan.

Comment 005-10: One commenter pointed out that in several places in Part 52 an applicant is required to provide “information necessary to demonstrate technical resolutions of those unresolved safety issues and medium- and high- priority generic safety issues.” This evaluation has been interpreted to include medium/high priority generic safety issues (GSIs), regardless of whether they have been resolved or not. The requirement to address “resolved” GSIs imposes a burden on an applicant with no associated benefit. Since new plant designs must comply with applicable regulatory requirements, they will, by definition, comply with the bases for resolution of previous GSIs. The commenter suggested that this requirement should be changed to cover only unresolved GSIs that are applicable to the design.

NRC Response: The NRC does not agree with this comment. The resolution of GSIs was determined based on current operating plants and those resolutions may not apply to future plants with new and different design features. The future applicants need to address how their plant design resolves each of the medium/high priority GSIs.

Comment 005-11: One commenter noted that in several places in Part 52 an applicant is required to show that operating experience has been taken into account in a new plant design, including “comparable international operating experience.” If the NRC becomes aware of international operating experience that it believes is relevant to one or more new plant designs, the NRC should identify that experience (e.g., by means of a generic letter) for consideration by an applicant. The current open-ended requirement should be deleted. If, however, the NRC determines international operating experience must be considered, the staff should be instructed to permit applicants to use relevant experience gained outside the United States to justify the use of new technologies in U.S. plants. Consideration of such information should include these “positive” aspects of international experience as well as the implied “negative” aspects of the current wording of the rule.

NRC Response: The NRC does not agree with this comment. As explained above, the portion of the requirement for international operating experience, only applies to nuclear plant designs that are not based on or are not evolutions of plants that are operating in the United States. The NRC’s generic letters may not address operational insights for those non-U.S. designs. Therefore, the NRC expects those applications to address how insights from any relevant international operating experience have been incorporated into their design.

Provisions Authorizing Open-ended Information Requirements

Comment 007-19: Several commenters noted that proposed 10 CFR§ 52.17(d), 52.79(a)(42), 52.137(a)(27) and 52.157(p) would allow the NRC to require applicants for an Early Site Permit (ESP) COL, standard design approval and manufacturing license to include “any information beyond” that specified in application requirements. The commenters stated that the proposed rule would establish an open-ended provision that essentially would confer upon the NRC staff the authority to set ad hoc requirements outside the rulemaking process. The commenters stated that such open-ended discretion on the part of the staff to require information beyond that specified in the regulation is inconsistent with the requirements of the Administrative Procedures Act and that the NOPR fails to justify these proposed new requirements.

The commenters stated that to the extent that additional information may be necessary during the NRC staff review of an application, the staff already has a “request for additional information” process that may be applied to Part 52 applications. This process is codified in 10 CFR 2.102(a). Furthermore, the commenters noted that the staff stated in its comments in its December 27, 2005, response to the Commission’s SRM, that the NRC “has inherent authority to require submission of additional information, upon a determination that it is necessary.” Thus, the commenters concluded that no additional regulatory authority is needed for the NRC staff to request additional information necessary to complete its review of an application.

The commenters suggested that these proposed requirements should be deleted. For the same reason, and because the NRC and the industry now have substantial experience with the design certification process, the similar requirement in existing § 52.47(a)(3) should be deleted.

NRC Response: The Commission disagrees with the commenter's suggestion that these provisions would confer upon the NRC staff the authority to require applicants to comply with either arbitrary and capricious information requests, or information requests on matters outside the regulatory purview of the NRC. No federal administrative agency has the authority to act in derogation of the Administrative Procedure Act or in excess of the powers delegated to it by Congress in applicable federal statutes. Nor does an agency possess the authority to adopt a regulation which effectively grants itself dispensation from compliance with applicable statutes.

Nonetheless, the Commission has decided that the disputed provisions in the proposed rule are unnecessary, because the NRC staff already possesses the authority under § 2.102(a) authority to require submission of necessary information. Accordingly, proposed § 52.17(d), § 52.47(a)(27)(same as § 52.47(a)(3) in the 1989 Part 52 rule), § 52.79(a)(42), § 52.137(a)(27), § 52.157(p) are not included in the final rule.

New Requirements for Applicants to Demonstrate Technical Qualifications

Comment 007-27: Several commenters noted that §§ 52.24(a)(4), 52.47(a)(23), 52.54(a)(4), 52.137(a)(23) and 2.104(d)(v) of the proposed rule would impose requirements for an ESP applicant, design approval applicant, and design certification applicant to demonstrate technical qualifications. The commenters stated that the Supplementary Information for the proposed rule neither explains nor justifies the purpose of these proposed provisions.

The commenters believe these proposed changes are inconsistent with the provisions in proposed 10 CFR 50.40 regarding technical qualifications for applicants. The commenters stated that “proposed § 50.40(b)—correctly—does not specify that an applicant for an early site permit, a design certification, or a design approval need demonstrate technical qualifications.” The commenters went on to state that these proposed amendments also appear inconsistent with Section 182.a of the Atomic Energy Act, which does not require that applicants for an ESP, design certification, or design approval demonstrate their technical qualifications; rather, the statute imposes that requirement only upon applicants for an NRC license.

The commenters stated further that if promulgated, these proposed changes would impose a new requirement on the applicants in question. The commenters noted that existing ESP applicants and design certification applicants were not required to demonstrate their technical qualifications. The commenters also noted that there does not appear to be a reason to impose such an additional requirement on future ESP and design certification applicants. The commenters stated that Industry is unaware of any problem here that the proposed new requirements are needed to resolve.

The commenters object to these additional requirements for ESP holders because they are not authorized to conduct any safety-related construction activities (see 10 CFR 52.25), and object to the additional requirements for design certification and design approval applicants for slightly different reasons. The commenters stated that a design certification is a rulemaking activity, not a license, and the design certification applicant will not necessarily be supplying a reactor to a future COL applicant. Instead, under 10 CFR 52.73, another entity may be the reactor vendor, and the COL applicant will need to demonstrate the technical qualifications of that entity (as well as its other primary contractors). Similarly, if the COL applicant references a standard design approval, it will need to demonstrate the technical qualifications of the vendor.

Thus, the commenters concluded that there is no reason for an applicant for an ESP, design certification, or design approval to demonstrate its technical qualifications at the time it submits its ESP application. Instead, the commenters suggested that the COL applicant will need to demonstrate its technical qualifications and those of its reactor vendor. The commenters believe that deferral of such a demonstration until the COL stage is especially appropriate, since the technical qualifications of the vendor and ESP holder may change substantially during the 15- to 20-year interval between the issuance of the ESP and/or design approval and the submission of the COL application.

The commenters recommended that the NRC delete the proposed requirement in §§ 52.24(a)(4), 52.47(a)(23), 52.54(a)(4), 52.137(a)(23) and 2.104(d)(v) discussed above. At a minimum, the commenters suggested that proposed § 52.24(a)(4) and 2.104(d)(v) requirements pertaining to ESP applicants should be deleted.

NRC Response: The NRC disagrees with this comment. Although the NRC agrees that the AEA imposes the technical qualification finding specifically for license applicants, it does not preclude the NRC from a determination that such a finding is also necessary in other contexts. The application for an ESP, design approval, or design certification may become part of a COL application, if referenced, and the applicant will create information that may become the bases for a future license. Therefore, the applicant must be qualified to perform design, analyses, safety determinations, and siting determinations. Accordingly, the NRC has concluded that a technical qualification finding needs to be made for these

New Requirements for Control of Radioactive Effluents

Comment 007-32: Several commenters noted that proposed §§ 52.47(a)(9) and (a)(10) and §§ 52.137(a)(9) and (a)(10) would require a design certification or standard design applicant to (1) describe the kinds and quantities of radioactive materials expected to be produced and used in the construction and operation and the design features for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR Part 20, and (2) provide information on the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e). The commenters stated that currently, 10 CFR 50.34(b)(3) requires that an application for an operating license include information in the FSAR that addresses the “kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in Part 20 of this chapter.” The § 50.34(a) requirements for a construction permit application do not contain a corresponding requirement for radioactive materials produced during construction. The NRC proposes no changes to the provisions in §§ 50.34(a) or (b).

The commenters noted that the proposed changes would also tailor the current Part 50 requirements for design certifications and design approvals by requiring that applications describe design features (rather than “means”) for controlling and limiting radioactive effluents and radiation exposures. Based upon comments made by the NRC at the workshop on March 14, 2006 (Tr. 152-153), the commenters understood that by this change, the NRC staff did not intend to impose different effluent requirements on applicants for design certification and design approvals than on other applicants. Rather, the commenters understood that NRC’s intent was to make clear that design certification and design approval applicants would

not be expected to describe “means” for controlling and limiting effluents that are outside the scope of the standard design (e.g., procedural controls, training, etc.). Nevertheless, the commenters believe that the language in the proposed rule might be construed otherwise. To avoid any implication that a new requirement is being imposed upon applicants for a design certification or standard design, the commenters suggested that the proposed amendments should be modified as discussed below.

The commenters suggested that the changes would impose new requirements for controlling effluents during both construction and operation (only operation is included in the current Part 50 requirements), and that no basis was provided for adding requirements on the construction phase, and doing so would be inconsistent with existing requirements in § 50.34(a) and proposed § 52.79(a)(3). The commenters suggested that proposed §§ 52.47(a)(9) and 52.137(a)(9) should be modified consistent with existing requirements.

Furthermore, the commenters believe that the “proposed rule is not internally consistent.” The commenters noted that proposed changes to 10 CFR Part 50, Appendix I, state that §§ 52.47 and 52.137 provide that applications for design certification and design approval “shall include a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems.” The commenters suggested that the proposed change to Appendix I should be modified to be consistent with §§ 52.47(a)(10) and 52.137(a)(10).

NRC Response: Although the NRC does not agree that proposed §§ 52.47(a)(9) and 52.137(a)(9) would impose new requirements on controlling effluents, the final rule language in §§ 52.47(a)(5) and 52.137(a)(5) have been revised to be consistent with the language in § 50.34(b)(3). As explained by the NRC at the workshop on March 14, 2006, the focus of the review for design approvals and design certifications will be on the design features used for controlling radioactive effluents. The procedures for control of radioactive effluents will be reviewed as part of the combined license application.

New Requirements for an Applicant for an ESP of Design Certification to Describe its Quality Assurance (QA) Program

Comment 007-37: Several commenters noted that proposed Section 50.55(f) would impose requirements on the quality assurance program, as described or referenced in the safety analysis report, on holders of an ESP, a manufacturing license, or a combined license (up to issuance of the § 52.103(g) finding, when the requirements of 10 CFR 50.54(a) would apply). The commenters also noted that §§ 52.17(a)(1)(xii), 52.47(a)(21), 52.137(a)(21), 52.157(e)(17) and Appendix B to Part 50 in the proposed rule would impose a new requirement on an ESP applicant, a design certification applicant, an applicant for design approval, and an applicant for a manufacturing license to describe the quality assurance program under Appendix B to Part 50 for ESP site activities, design activities, and manufacturing activities respectively.

The commenters stated that as written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program. The commenters did not believe that it was the intent of the NRC to apply the Appendix B requirements so broadly. Therefore, the commenters recommended that the NRC revise these provisions to clarify that the Appendix B QA program would apply only to activities affecting the

safety-related functions of the structures, systems, and components (SSCs), and not to all ESP site activities, design activities, and construction activities. The commenters' recommended changes would make the new Part 52 requirements consistent with existing Appendix B, which states, "The pertinent [QA] requirements of this appendix apply to all activities affecting the safety-related functions [of SSCs]."

Additionally, the commenters also stated that these proposals could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B. However, the commenters stated that not all of those criteria are applicable to each of the applicants. The commenters noted as examples that Criterion III on design control, Criterion IX on special processes, and some of the other criteria are clearly inapplicable to ESP applicants. According to the commenters, Criterion IX, Criterion X on inspections, and some of the other criteria would also not be applicable to applicants for design certification and design approval. The commenters did not believe that it was NRC's intent to apply the Appendix B requirements so broadly. Therefore, the commenters recommended that the NRC modify the language in the proposed rule to clarify that the applicant need only establish and implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant.

Comment 007-38: Several commenters noted that proposed § 50.55(f) would impose requirements on the quality assurance (QA) program, as described or referenced in the safety analysis report, on holders of an ESP, a manufacturing license, or a COL (up to issuance of the § 52.103(g) finding, when the requirements of 10 CFR 50.54(a) would apply). The commenters also noted that §§ 52.17(a)(1)(xii), 52.47(a)(21), 52.137(a)(21), 52.157(e)(17), and Appendix B to Part 50 in the proposed rule would impose a new requirement on an ESP applicant, a design certification applicant, an applicant for design approval, and an applicant for a manufacturing license to describe the QA program under Appendix B to Part 50 for ESP site activities, design activities, and manufacturing activities respectively.

The commenters noted that proposed § 52.17(a)(1)(xii) would require an ESP applicant to provide "a description of the quality assurance program applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site." The commenters stated that this provision is ambiguous and could be incorrectly interpreted as applying to all site-related activities. Furthermore, the commenters stated that on its face, this language would require a QA program for an ESP to have a broader scope than a QA program for a CP or COL. The commenters stated that "no justification has been provided for this expansion of the scope of the ESP QA program" and that "such an expansion is unwarranted." The commenters stated that the scope of an ESP QA program should be no greater than the scope of a QA program for a CP or COL.

NRC Response: The NRC does not agree that, as written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program, as opposed to applying only to activities affecting the safety-related functions of the structures, systems, and components. The commenter quoted the following words from the existing language in Appendix B, "The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components,"

[emphasis added], as evidence that the existing requirements relate only to safety-related SSCs. These words have not been removed from Appendix B and therefore apply to all of the new Appendix B requirements for ESPs, design certifications, design approvals, and manufacturing licenses. The NRC notes that the requirements in the current versions of §§ 50.34(a)(7) and 50.55(f) applicable to construction permits do not contain qualifiers that the Appendix B QA requirements apply only to activities affecting safety-related SSCs because such a qualifier is unnecessary given the language in Appendix B to Part 50. In creating parallel requirements for the Part 52 licensing and approval processes, the NRC tried to be as consistent as possible with the existing requirements for Part 50 applicants and licensees.

NEI also commented that some of the proposed language regarding QA requirements could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B and noted that not all of those criteria are applicable to each of the applicants.

The NRC does not agree that the proposed rule language regarding QA requirements for an ESP, design certification, design approval, or manufacturing license needs to be modified. Each of the subject provisions (52.17, 52.47, 52.137, and 52.157) states that the description of the quality assurance program must include a discussion of how the applicable requirements of Appendix B will be satisfied [emphasis added]. Therefore, the NRC believes it is clear that it was not the intent to apply the Appendix B requirements too broadly and that the language in the proposed rule is sufficient to indicate that the applicant need only implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant. Therefore, no changes have been made to these sections in the final rule.

Note that on July 19, 2006, the commenter (NEI) informed the NRC by e-mail (ML062710327) that it could not recreate the basis for some of the words in its May 30, 2006 recommended language for 52.17(a)(i)(xii) and that, for purposes of dispositioning this comment, the NRC should ignore them.

Deletion of the Option of Using Appendix Q and Subpart F by COL Applicants

Comment 007-43: Several commenters noted that the propose rule would delete 10 CFR Part 52, Appendix Q, which allows a Part 52 applicant to request early site suitability review. In addition, the commenters noted that the proposed rule would not clarify that Subpart F of 10 CFR Part 2 may be used by COL applicants. The commenters stated that while no applicant has yet expressed an intent to use the early site review process in Appendix Q or the process in Subpart F to Part 2 for partial decisions on site suitability issues, that these processes may provide important flexibility for early and efficient consideration of site suitability issues for COL applicants. The commenters asserted that there is no reason to eliminate this flexibility, and no harm is caused by allowing Part 52 applicants to utilize these provisions, therefore the commenters recommended that the NRC retain Appendix Q in Part 52, as well as in Part 50.

The commenters noted that both of these regulations allow critical path site issues to be reviewed by NRC in advance of the submission of a COL application (COLA), in cases where the applicant's schedule or other considerations do not allow it to complete the ESP process in advance of the COLA. Further, the commenters stated that utilization of Appendix Q or

Subpart F in the context of a COLA could allow the NRC staff to more efficiently utilize its resources to focus early review of site issues only on those issues sought by the applicant, rather than the full scope of issues required by an application for an ESP.

The commenters noted that in the August 2005 draft of the proposed rule, the NRC indicated changes in 10 CFR Part 2 Subpart F that would have allowed the Subpart to be used in the Part 52 COL process. The commenters stated that this change was not part of the proposed rule. Thus, the commenters concluded, "one could (erroneously) conclude that Part 2, Subpart F, is only applicable to the Part 50 construction permit process." The commenters suggested that the August 2005 draft revisions to Subpart F be incorporated into the final Part 52 rule to clarify its continuing availability to Part 52 applicants.

The commenters recommended changes that they assert would specifically allow an application for an ESP or COL to reference a review conducted in accordance with Appendix Q to Part 50. The commenters believe that their recommended changes would also modify the provisions in Subpart F of Part 2 explicitly to allow its use in Part 52 actions. Based upon the statements provided by the NRC at the workshop on March 14, 2006 (Tr. 23-24), the commenters understood that it was the NRC's intent to allow Part 52 applicants to use Subpart F.

NRC Response: In response to commenters concerns, the NRC has decided not to remove Appendix Q from Part 52 in the final rule. Appendix Q has been included in Part 52 in the final rule and conforming changes have been made to make it available for use by prospective early site permits and combined license applicants. Such applicants will have the same option for early resolution of site suitability issues as is currently available to construction permit applicants. This will provide early site permit and combined license applicants with additional flexibility to seek early resolution of issues.

The Commission agrees that § 2.101(a-1) and subpart F of Part 2 should be modified to allow applicants for combined licenses under Part 52 to take advantage of those provisions. Both § 2.101(a-1) and Subpart F have been revised in the final rule so that combined license applicants may avail themselves of these procedural alternatives, albeit somewhat differently than the approach recommended by the commenter. Inasmuch as the revisions are to the Commission's rules of procedure and practice, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

The Requirement to Evaluate Applications Against the SRP Should Only Apply to Light Water Reactors

Comments 007-63 and 007-79: Several commenters noted that proposed §§ 52.47(a)(26), 52.137(a)(26), and 52.157(p) state that a design certification, design approval, and manufacturing license application shall include an evaluation of the standard plant design against the SRP in effect 6 months prior to the docket date of the application.

The commenters noted that these proposed provisions are similar to 10 CFR 50.34(h). However, the commenters stated that unlike § 50.34(h), the provisions in the proposed sections are not limited to applicants for light-water reactors (LWRs). The commenters suggested that

this may have been an inadvertent oversight by the NRC. The commenters noted that “the analogous provision for COL applicants, § 52.79(a)(1)(41), correctly limits this requirement to LWRs.”

The commenters suggested that, similar to the requirement in § 50.34(h), the requirement in proposed §§ 52.47(a)(26), 52.137(a)(26), and 52.157(p) should be explicitly limited to LWRs. The commenters continued that since the SRP was developed solely for light water reactors, “it would be inappropriate and serve no useful purpose to require design certification applicants for other types of reactors (e.g., high-temperature gas cooled reactors) to evaluate their design against the SRP.”

NRC Response: The NRC agrees with the commenters and revised the subject provisions to be applicable to light-water cooled nuclear power plants. However, the NRC disagrees with the commenters that applicants for non-LWR designs, such as the PBMR, should not be required to evaluate their designs against the SRP. First, there are a large number of areas within the SRP that are “technology-neutral” in the sense that the SRP applies regardless of the technology of the reactor under review. Most of the requirements in Part 50 are, for the most part, technology neutral, and have been applied in past AEC/NRC licensing actions for non-LWR designs, such as Peach Bottom, Fort St. Vrain, and the Clinch River Breeder Reactor. At least one potential combined license applicant (Exelon) has concluded that most of the technical requirements in Part 50 would be applicable to non-LWR designs that they were considering for a new nuclear power plant. Each of the current standard design certification applicants identified several technical requirements which they believed are not technically applicable to their design. The Commission provided dispensation from compliance with these requirements by including appropriate exemptions in each of final design certification rules. The same process may be used by future applicants for design certifications, including applicants for certification of non-LWR designs.

Second, the SRP is not a requirement, and indeed, the regulation simply requires the applicant to identify where the design has diverged from the guidance in the SRP. The purpose of the SRP evaluation requirement is one of resources and planning: it allows the NRC staff to estimate application review areas which may require special resources, and a greater period of time to perform the safety review. The commenter did not set forth more specific reasons why the underlying goals of the requirement for evaluation against the SRP would not be served in the case on non-LWR designs. See Section V.C.8.f of supplementary information for more discussion on this requirement.

Support for Conforming Changes and Other Beneficial Proposals

Comments 007-70 and 007-79: Several commenters suggested one additional change to Part 52 that it and its constituents consider necessary to ensure that the regulations are consistent and conform to the Energy Policy Act of 2005 and previous rulemakings. The commenters suggested that the NRC include changes to the design certification rules and the change processes in Part 52 to be consistent with the concepts of the revised 10 CFR 50.59. The commenters noted that the NRC deferred these changes from the § 50.59 rule change. [See 64 FR 53582, 53601, October 4, 1999] The commenters believe that the proposed rule adequately addresses this issue. Several commenters also stated that the industry considers the changes in the NOPR in Appendix A, B, and C to Part 52, regarding identified corrections to

design certification rules, such as to Section X, Records and Reporting, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.3.1 General Provisions

Expansion of the Applicability of Requirements for Employee Protection

Comment 007-17: Several commenters noted that proposed 10 CFR § 52.5(a) would prohibit discrimination by a Commission licensee, holder of a standard design approval, an applicant for a license, standard design certification, or standard design approval, a contractor or subcontractor of a Commission licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, against an employee for engaging in certain protected activities. The commenters also noted that proposed changes to Part 19 (especially proposed 10 CFR § 19.20) includes parallel provisions.

The commenters stated that application of employee protection requirements to design certification applicants and applicants for design approval “is inappropriate and unauthorized under Section 211 of the Energy Reorganization Act (the Act).” The commenters noted that Section 211 of the Act applies to “employers,” and that the Act defines “employer” as including an NRC licensee or applicant for license, and contractors or subcontractors of such a licensee or applicant, and certain Department of Energy contractors or subcontractors. The commenters stated that an applicant for a design certification or design approval is not encompassed within any of the provisions in Section 211.

The commenters further stated that an applicant for design certification is fundamentally different from an applicant for a license. The commenters stated that design certification occurs through rulemaking, and as a result, a design certification applicant has no proprietary interest in a design certification. The commenters noted that as indicated by provisions such as 10 CFR 52.73, a design certification can be utilized by any qualified vendor, and the design certification applicant will not necessarily be the ultimate designer or supplier of a plant that references the design certification. The commenters concluded that it would therefore be inappropriate to apply the provisions in proposed § 52.5 to design certification applicants.

The commenters stated that the proposed rule would have the effect of applying licensing provisions to design certification rulemaking. The commenters concluded that this is a fundamental shift in the nature of design certification that “is inappropriate, is unfair to design certification applicants, and should be rejected.”

The commenters finished by stating that if the NRC does not agree, the proposed revision should at least be modified to mitigate some of the detrimental features. In particular, the commenters suggested that at most, § 52.5(a) should apply only during those periods in which the applicant for design certification or design approval is actively engaged in regulated activities. The commenters also recommended that parallel changes be made in proposed 10 CFR Part 19.

NRC Response: The NRC disagrees with the comment that application of employee protection requirements to design certification applicants and applicants for design approval “is inappropriate and unauthorized under Section 211 of the Energy Reorganization Act (the Act). As stated in the Supplementary Information section of the proposed rule, the NRC believes that its regulatory authority under Section 211 and Section 401 of the 1974 ERA is much broader than the current scope of Part 19. The anti-discrimination proscriptions in Section 211 of the ERA apply to any “employer,” which the NRC regards as including non-licensee entities otherwise regulated by the NRC, such as applicants for and holders of standard design approvals, and applicants for standard design certifications. The Commission believes that the use of the term, “includes,” in paragraph (a)(2) of Section 211 of the 1974 ERA was not intended to be an exclusive list of the persons and entities subject to the anti-discrimination provisions in that section. The House Report on H.R. 776, which was adopted by Congress as the Energy Policy Act of 1992, states:

[Title V] also broadens the coverage of existing whistle blower protection provisions to include...any other employer engaged in any activity under the Energy Reorganization Act of the Atomic Energy Act of 1954.

H.Rep. No. 102-474, Part 8, 102d Congress, 2d Sess., at 78-79 (1992) (emphasis added). There was no discussion of the statutory language in the conference report. H.R. Conf. Rep. No.102-1018, 102d Cong., 2d Sess. (1992). Commenters did not provide any reason why the Commission’s interpretation of “includes” is incorrect. The Commission’s interpretation is reasonable because design certifications and design approvals help to form the basis for NRC safety determinations with respect to licensing of nuclear power plants referencing the design certifications or design approvals. Accordingly, in the absence of any showing that the Commission’s interpretation is incorrect or otherwise unreasonable, the NRC rejects the comments and has made no changes in the final rule. The NRC also does not agree with the commenters’ suggestion that § 52.5(a) should apply only during those periods in which the applicant for design certification or design approval is actively engaged in regulated activities. The NRC believes that employees should be able to raise safety concerns related to a design approval or design certification at any time without fear of retaliation.

Beneficial Changes Proposed for Part 52

Comment 007-74: Several commenters stated that the industry considers the changes in the NOPR in § 52.1, regarding definitions, and in § 52.7, regarding the applicability of the § 50.12 exemption process, to be beneficial . The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.3.2 Subpart A - ESP

Loss of “Finality” for Environmental Issues

Comments 002-1, 002-2, 002-5, 010-1, 012-1, 006, 009, and 013:² Several commenters expressed concerns about the loss of finality previously awarded to safety and environmental issues addressed in an ESP, specifically that issues addressed in an ESP would no longer be treated as resolved in subsequent COLs. Commenters stated that specific language in proposed §§ 51.50(c)(1)(iii), 51.107(b)(3) and 52.39(a)(2)(v) was contrary to the ESP finality principle of existing Part 52 (54 FR 15372, 15373, 1989). Commenters believed that the NRC should not eliminate current §§ 52.39(a)(2), 52.79(a)(1), and 52.89 with respect to previously resolved environmental issues, and should not promulgate proposed §§ 52.39(c)(1)(v) and 51.107(b)(3) as written. These commenters stated that the changes would, if implemented, lead to unnecessary and inefficient reconsideration, re-review, and possible re-litigation of issues that had been resolved in an ESP proceeding, and could deter future use of the ESP process. Commenters expressed concern that if enacted, the proposed amendments would allow, as long as the pleading standards were met, any intervenor to litigate a previously evaluated environmental issue by alleging that new information existed which altered the prior conclusions. (71 FR 12826) Commenters expressed concern that NRC staff had suggested that to allow a realization of prior ESP findings, a COL applicant referencing an ESP would be required to update its previous environmental report to present and analyze final plant design information, regardless of whether it fell within the bounds of the prior evaluation. Commenters expressed support for current rules that avoided reconsideration of environmental issues in a COL application when those issues had previously been assessed and resolved in an ESP proceeding.

One commenter suggested the NRC should provide direction to the NRC staff that it is not necessary for the staff to examine or revalidate previously resolved environmental issues, or perform an independent search for new information. The commenter stated that where environmental impacts were evaluated at the ESP stage, any supplemental EIS at the COL stage should be limited only to those matters requiring supplementation. The commenter further noted that the NRC staff should rely upon comments from the public and consulting agencies to identify any areas where supplementation might be needed. The commenter stated that if no person identified a need to supplement the discussion of an impact addressed in the ESP EIS, there should be no need for any discussion of that impact in the EIS supplement at the COL stage.

NRC Response: The NRC agrees in part with the commenters. Upon further consideration of the proposed rule language and discussions with stakeholders in NRC public meetings, the NRC agrees that the rule language in §§ 51.50(c)(1), 51.107(b)(3) and 52.39(a)(2)(v) should be modified to more clearly reflect the finality of environmental issues resolved in an ESP. However, the NRC does not agree that it should retain the rule language in current

²Commenters 006, 009, 010, 012, and 013 also fully endorsed and supported NEI's comments submitted on May 16, 2006. Therefore, all of these commenters are included in each of NEI's May 16, 2006 comments (comment number 002). For simplicity, these comment numbers are not repeated in this document for each comment.

§§ 52.39(a)(2), 52.79(a)(2), and 52.89 because it did not appropriately reflect the NRC's obligations under NEPA.

Instead, the final rule limits, in § 52.39(c)(1)(v), environmental contentions that may be litigated to any significant environmental issue related to the impacts of construction and operation of the facility that was not previously resolved in the proceeding on the early site permit application, or any issue involving the impacts of construction and operation of the facility that was previously resolved in the proceeding on the early site permit application for which significant new information has been identified. The NRC believes that its regulations and the applicable case law interpreting the National Environment Policy Act of 1969, as amended (NEPA), allow the NRC to incorporate the ESP EIS by reference in the combined license EIS. However, the NRC must address identify any significant new information for issues that were resolved in the ESP EIS. For these reasons, the NRC believes the final rule language appropriately captures the agency's NEPA obligations.

For similar reasons, the NRC does not agree that it should rely upon comments from the public and consulting agencies to identify any areas where supplementation of an ESP EIS might be needed at the COL stage and that, if no person identified a need to supplement the discussion of an impact addressed in the ESP EIS, there should be no need for any discussion of that impact in the EIS supplement at the COL stage. Instead, the NRC has revised § 51.50(c) in the final rule to require a combined license application that references an early site permit to contain any significant new information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding and a description of the process used to identify new and significant information regarding the NRC's conclusions in the early site permit environmental impact statement. While the NRC is ultimately responsible for completing any required NEPA review, the combined license applicant must identify whether there is new and significant information on a previously resolved issue. A combined license applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form for issues for which the combined license applicant does not identify any new and significant information. The NRC believes that the final rule language in § 52.39 and Part 51 appropriately captures the agency's NEPA obligations.

Comment 005-14: A commenter questioned whether there are limitations on the NRC's ability to evaluate and "inquire into the continued validity" of the information supporting an environmental impact statement for an ESP.

NRC Response: Upon further consideration, the NRC has removed this language from the Supplementary Information section of the final rule because it implied a overly broad view of the NRC's obligations under NEPA for the review of a COL application referencing an ESP.

Petitions for Waiver of Finality Rule

Comments 002-9, 002-11, 002-12, 002-13, 002-14, 002-15, 002-16, 002-95: Commenters believed the NRC should modify the final rule to reflect that persons seeking to reopen previously resolved environmental issues in a COL proceeding must petition the NRC for a waiver of the finality rules (currently, 10 CFR§ 52.39(a)(2), 52.79(a)(1), and 52.89). They

argued that if the applicant, the NRC staff, or a member of the public identified new information that they believed altered the evaluation of an environmental issue addressed in the ESP EIS, and if this new information did not relate to a design feature exceeding the parameters specified in the ESP, then a waiver of the finality rules should be obtained from the NRC in order to allow reconsideration of the previously analyzed impact. Commenters stated that consistent with federal case law on when an agency must prepare a supplement to an EIS, the NRC should grant the waiver only if the new information presented a “seriously different picture of the environmental impact” of granting a COL than what was previously envisioned. (*S. Trenton Residents*, 176 F.3d at 663; *New River*, 373 F.3d at 1330). Commenters stated that in accordance with the NRC’s Rules of Practice, the NRC should be able to grant a waiver request only if it were supported by an affidavit establishing the special circumstances with particularity and making a prima facie showing that the rule should be waived. (10 C.F.R. § 2.335(b),(c)). They described these procedural safeguards as needed and appropriate to preserve the current rule’s objective of allowing early resolution of environmental issues.

Furthermore, the commenters argued that the NRC’s consideration of the new information in the course of evaluating a waiver request would be consistent with federal case law that allows agencies to employ non-NEPA documentation (i.e., documentation aside from an EA or supplemental EIS and not subject to NEPA public participation requirements) to determine whether alleged new impacts are significant enough to require the preparation of supplemental NEPA documentation and explain why not.

Alternately, one commenter explained their support for the use of waivers as follows: “requiring a waiver would also be consistent with the approach that the NRC has followed in license renewal proceedings, where the NRC staff (or an intervenor) is required to apply to the Commission for a waiver before any Category 1 issue (i.e., any issue previously resolved generically) can be reconsidered, based on significant and new information. See SECY-93-032 at 3-4; 61 FR 28467, 28470 (1996). This approach would allow supplementation of the ESP EIS where appropriate, while maintaining the preclusive effect of the Part 52 regulations. In the Supplementary Information in the rulemaking notice, the NRC recognizes the applicability of the license renewal environmental review process to the review of COL applications referencing ESPs (71 FR 12826), and the commenters agree that the NRC’s license renewal approach is fully applicable here.”

NRC Response: The NRC does not agree with the commenters’ suggestion that persons seeking to reopen previously resolved environmental issues in a COL proceeding should be required to petition the NRC for a waiver of the finality rules. The Commission’s view is that an EIS prepared for a combined license referencing an ESP must address significant new information that affects the evaluation of an environmental issue resolved in the ESP EIS, but only if that environmental issue is relevant to the decision to issue the combined license. For example, information related only to siting that was resolved in the ESP proceeding is not relevant to the decision to issue the combined license, because the siting issue was finally determined, from both a safety and environmental standpoint, as part of the issuance of the ESP. By contrast, information which a public stakeholder claims is new and significant only with respect to the matters resolved in the early site permit proceeding will be addressed by the Commission as part of the routine scoping and public comment process. The Commission’s inquiry, with respect to such information, will be - as suggested by the commenters - directed at whether the information presents a “seriously different picture of the environmental impact,” or otherwise could reasonably lead to a different conclusion with respect to the underlying decision

to issue the ESP in its current form. The Commission will not, however, allow such matters to be addressed in the adjudicatory hearing for issuance of a combined license. Instead, they will be treated as petitions for modification of the early site permit under §52.39(c)(2). The petition will not be considered by the Commission unless the petitioner had raised this matter in either the scoping process or public comment process with as much detail and information as would otherwise be required to support the “basis requirement” for a contention in 10 CFR 2.309. This is essentially the same as the “waiver” process advocated by the commenters, and is based upon former § 52.39(a)(2)(iii).

With regard to the comparison with the license renewal process, for license renewal, the NRC performed the analysis of environmental effects during the renewal period for each of the operating plants; the NRC also had the benefit of the operating experience of over 100 units for an extended period of time to support its analyses. The analysis based on this information was codified and use of the waiver process to challenge this information was appropriate. For new plants where the environmental impacts of construction and operation were resolved in the ESP proceeding, the conclusions were based on analytical methods and assumptions regarding the design, construction and operation of the facility and some of the information about the design, construction practices, and proposed operations were not well known at the time of the ESP application. Therefore, it is not analogous to the license renewal situation.

Comments 011-3 and 011-4: A commenter noted that in § 52.39 (page 12783), in C.4.g, in the last paragraph, the proposed rule states the proposed revision will be in § 52.39(d), but the commenter suggests that it is actually in § 52.39(e). The commenter also noted that in C.4.g, and the reference rule sections, the text discusses requirements related to information requests with a focus on safety information. The commenter asked whether there is, or should be, an equivalent requirement for environmental information.

NRC Response: The NRC agrees that all references to this provision in § 52.39 should be to paragraph (e) and has made the correction in the final rule. The requirements in §52.39(e) are based on the requirements in current § 50.54(f). Section 50.54 addresses condition to be placed on licenses related to safety requirements. Section 50.54 does not address environmental conditions, which are addressed in § 50.36b. A provision similar to 50.54(f) does not currently exist for environmental conditions and the NRC did not propose to add one in this rulemaking.

Duplicative Review in Applications for ESPs or Design Certifications and COL Applications

Comment 012-11: A commenter stated that in order to promote efficiency and standardization, the NRC should include in any final rule a provision providing that if a COL application references a pending application for an ESP or design certification, the COL proceeding will not include duplicative review or litigation of issues being resolved in the other, referenced proceedings. The commenter stated that alternatively, if the NRC does not address this issue by rule, it should issue a policy statement providing appropriate guidance to the NRC staff and Atomic Safety and Licensing Board to avoid duplicative reviews in such cases.

The commenter and other companies are currently preparing COL applications under DOE's 2010 program, which is intended to lead to the deployment of new units, particularly Gen II+ units, in a timeframe that is likely to lead to parallel COL, design certification, and ESP

proceedings. In addition, the commenter noted that the Energy Policy Act of 2005 provides incentives for the development of new units, which may affect the applicant's choice of schedule. The commenter noted as an example that in order to qualify for the production tax credit, a company must submit its COL application by the end of 2008. [See IRS Bulletin No. 2006-18 (May 1, 2006), Notice 2006-40] The commenter stated that COL applicants may not be able to wait until design certification proceedings for their selected technology or ESP proceedings for their selected sites are complete. The commenter acknowledged that while the NRC's procedures should not be dictated by these programs and incentives, it is reasonable for the NRC to take steps to ensure that its process is not an impediment to prompt deployment of the most current, passively safe designs. The commenter went on to state that if a design for which a design certification application has been submitted would be subject to duplicative review and litigation in a COL proceeding, attractive new designs like the Economic Simplified Boiling Water Reactor might be at a disadvantage and that similarly, the NRC should take steps to ensure that prompt consideration of site suitability issues is not deterred.

Further, the commenter stated that duplicative review of issues already being addressed in another referenced proceeding would be a costly and inefficient use of the NRC's resources, which are already likely to be challenged by the number of expected applications, and would constitute an undue burden to the applicant. The commenter stated that duplicative reviews could also lead to inconsistent results and loss of standardization. The commenter noted that Part 52 is intended to encourage standardized designs. The commenter stated that this objective would be frustrated for near-term COL applicants who are demonstrating the process and who would be required to obtain plant-specific design reviews in their COL proceedings.

The commenter also noted that avoiding duplicative reviews would be consistent with past NRC practice and case law. The commenter noted that in the Private Fuel Storage case, the NRC staff did not duplicate the review of the cask design issues that were being reviewed for a certificate of compliance. The commenter noted that in addition, case law has long held that Licensing Boards should not accept contentions which are or are about to become the subject of rulemaking. [See *Duke Energy Corp. (Oconee Nuclear Station, Units 1, 2, & 3)*, CLI-99-11, 49 N.R.C. 328, 345 (1999).] The commenter also noted that in *UCS v. AEC*, 499 F.2d 1069 (D.C. Cir. 1974), the DC Circuit upheld the Commission's discretion to exclude issues from consideration in a licensing proceeding when those issues are being considered in a rulemaking proceeding. The commenter stated that as a general matter, the NRC clearly has the discretion to define the scope of its proceedings. [*Bellotti v. NRC*, 725 F.2d 1380, 1381 (DC Cir. 1983).]

The commenter recommended that the NRC should amend 10 CFR§ 52.27(c) and 55.55(c) to exclude from the scope of review and hearing in a COL proceeding those issues that are being resolved in a pending ESP or design certification proceeding referenced in the COL application.

NRC Response: The Commission agrees with the commenter that under existing NRC caselaw, matters which are or about to become the subject of NRC rulemaking, such as a standard design certification, should not be the subject of admitted contentions in a nuclear power plant licensing proceeding. Potomac Electric Power Co. (Douglas Point Nuclear Generating Station, Units 1 and 2), ALAB-218, 8 AEC 79, 85, 89 (1974). However, there is no need for a rulemaking provision in Part 52 to establish the applicability of this principle to combined license proceedings. The caselaw of the NRC applies to all NRC proceedings, including future combined license proceedings referencing an application for a design

certification. Furthermore, this principle also applies in early site permit proceedings, and manufacturing license proceedings, but the commenter did not suggest that parallel provisions be adopted for those matters. Adopting the commenter's proposed changes to §§ 52.27 and 52.55, but not to Subparts A and F of Part 52 could lead to the erroneous conclusion that the principle does not apply in those types of proceedings.

The Commission disagrees with the commenter's proposal for a rulemaking provision that would preclude duplicative reviews and litigation of issues in a combined license proceeding which references an early site permit application. Although the Commission agrees that duplicative review should be avoided, the particular manner in which duplication would be avoided depends upon the circumstances present at the time that the early site permit is referenced by the combined license application. For example, if an early site permit and a combined license application were filed simultaneously (or near simultaneously), the manner in which the Commission may notice and conduct the early site permit and combined license hearings (e.g., a consolidated hearing) may be quite different from the situation where the combined license application referencing the early site permit application is filed at the time of imminent issuance of the referenced early site permit. It would likely prove difficult to develop such rule language (or, as the commenter suggested as an alternative, a policy statement) that would be clearly and understandable to all stakeholders, especially in view of the fact that the Commission has no direct experience with combined license applications referencing early site permit applications. The Commission believes that the provisions in the Part 52 final rulemaking will largely address the concerns of the commenter with respect to duplicative reviews.

For these reasons, the Commission declines to adopt the commenter's proposal and no change to the final has been made in response to the comment.

Comment 013-3: A commenter urged the NRC to avoid reopening issues already resolved as a result of the NRC's design-centered approach or as a result of reviews of Early Site Permit (proposed § 52.27(c)) or Design Certification (proposed § 52.55(c)) applications.

NRC Response: In general, the Commission agrees with the commenter that the issues resolved in a standard design certification rulemaking should not be reopened in subsequent combined license, construction permit, or manufacturing license proceedings which reference the design certification rule.

The Commission also agrees with the implicit suggestion of the commenter that design matters that have been resolved by the NRC in a design centered approach should not ordinarily be "reopened" or otherwise reconsidered as part of each individual combined license application. To facilitate the design-centered approach, the Commission is retaining Appendix N in Part 52, and modify its provisions as well as those of Subpart D of Part 2. These provisions should address the commenter's suggestion for issue finality in the design-centered approach.

The Commission's position on issue resolution and finality with respect to early site permits is set forth in elsewhere as part of the NRC's response to comments on early site permit issue resolution and finality, and the NRC's response to Commission Question 9.

NRC Should Not Require ESP Applicants to Perform Radiation Consequences Analyses

Comment 007-13: Several commenters noted that proposed 10 CFR 52.17(a)(1)(ix) would require an ESP applicant to evaluate postulated fission product releases consistent with 10 CFR § 50.34 using containment leak rates and fission product cleanup systems. The commenters stated that modification of proposed § 52.17(a)(1) is needed to reflect the ability to seek and obtain an ESP without specifying the design to be built and without providing specific design information. The commenters stated that a lesson learned from the existing ESP proceedings is that final radiation consequence analyses should not be a requirement for ESP. Instead, the commenters suggested that Part 52 should allow such an analysis to be performed and provided for NRC review by ESP applicants if the requisite design-specific information is known. If not, and similar to the approach for addressing EP and security plans, the ESP applicant should be required to demonstrate that Part 100 requirements can be met by providing sample radiation consequence analyses based site characteristic atmospheric dispersion factors (X/Q).

The commenters stated that while they generally agree with the NRC staff on the acceptability of the plant parameter envelope (PPE) approach for ESP applicants who have not selected a specific design for their site, they do not believe that proposed § 52.17(a)(1) adequately reflects this approach. The commenters noted that under the PPE approach, an ESP applicant does not seek approval of the site for specific facilities; rather, bounding design information is used as a surrogate for actual facility information to support the ESP review and approval is sought for a reactor or reactors that fall within the PPE.

The commenters stated that, depending on the approach selected by an ESP applicant, the radiological consequence analyses that can meaningfully be performed and provided for NRC review are different. The commenters stated that ESP applications based on a specific design may be able to present complete radiological consequence analyses that demonstrate that Part 100 radiological dose criteria are met for the proposed site/design combination. Section 52.17(a)(1) should not require complete radiological consequence analyses even for applicants that seek approval of the site for a specific facility because the specified facility may not be a certified design. If the ESP application is based on a specific, non-certified design, the design-specific information necessary for complete radiological consequence analyses may not yet be available, or may be subject to change. NRC review and approval of accident sequences, release histories and related design-specific information would be expected in a design certification or combined license proceeding, not in an ESP proceeding. However, the commenters went on to say that if the ESP applicant has not selected a specific design, complete radiological consequence analyses, which require knowledge of design-specific accident sequences, release histories, etc., cannot be meaningfully accomplished. Instead, the commenters suggested that the focus for these ESP applicants should be on the site-related aspects of radiological consequence analyses, i.e., determination of site atmospheric dispersion characteristics.

The commenters stated that the determination that radiological dose consequence criteria are met can only be made when both the site and design are known. The commenters noted that the existing ESP applicants are using the PPE approach and have not specified a particular design as the basis for their applications. Their radiological consequence analyses are based

on bounding analyses; design-specific analyses will be required to be submitted in any combined license application referencing the ESPs.

The commenters suggested that for an ESP application, the acceptability of the site with respect to radiological dose consequence criteria should be dependent on the site characteristic X/Q, including any assumptions related to the structures, systems and components (SSCs) that bear significantly on the calculation of X/Q such as elevated release point and building locations associated with assumed wake effects. The commenters noted that at the COL stage, the site X/Q will need to be combined with the release history information provided in a design certification, or approved during the COL review of an uncertified design, to determine whether dose requirements are met for the specific plant.

The commenters stated that the NRC provides no explanation in the Supplementary Information as to why it would require an ESP applicant to evaluate postulated fission product releases using containment leak rates and fission product cleanup systems. The commenters stated that the provision is inappropriate and, as discussed above, is potentially impossible to satisfy for an ESP applicant using the PPE approach.

NRC Response: The NRC agrees that § 52.17(a)(1) should reflect the option for ESP applicants to use postulated design parameters in lieu of actual design information but notes that this allowance was provided for in the proposed rule. Specifically, § 52.17(a)(1)(i) states that the application must contain the specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used [emphasis added]. The NRC does not agree, however, that changes are needed to clarify the nature of radiological consequence analyses that are required of ESP applicants. This issue has been discussed with NEI in public meetings and in letters from the NRC dated February 5 and June 20, 2003 (ADAMS Accession Nos. ML030210341 and ML031150617), on the resolution of Early Site Permit Topic 7 (ESP-7), which involved guidance for satisfying 10 CFR 52.17(a)(1) requirements. The NRC staff also addressed the issue in SECY-03-0105, "Early Site Permit Application Readiness," dated June 24, 2003, and in NRC's August 4, 2003 letter to NEI providing the NRC's responses to NEI's comments on draft Review Standard (RS)-002, "Processing Applications for Early Site Permits," Sections 15 and 17.1.1 (ADAMS Accession No. ML031920465). During all of these discussions, the NRC has consistently maintained that dose consequence evaluation factors must be considered in an ESP application as required by § 52.17(a)(1).

The NRC's regulations in 10 CFR Part 100, "Reactor Site Criteria," present a framework that guides the NRC in its evaluation of the suitability of proposed sites for stationary power and test reactors. The regulations recognize the importance of accident considerations in reactor siting and key elements are the determination of the size of the exclusion area considering postulated accidents with a large fission product release within containment and the evaluation of the radiological consequences in terms of doses.

Accident considerations historically have been of key importance in reactor siting. Major developments in risk assessment, such as the issuance of the Reactor Safety Study (WASH-1400), and NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," as well as the occurrence of the Three Mile Island accident in 1979 and the accident at Unit 4 of the Chernobyl reactor in the Soviet Union in 1986, have heightened awareness, knowledge, and concerns in this area. Siting factors and criteria are important in assuring that

radiological doses from normal operation and postulated accidents will be acceptably low. In 1996, the NRC amended its regulations to update the criteria used in decisions regarding power reactor siting (61 FR 65176; December 11, 1996). In that rulemaking, the NRC modified source terms and dose calculation requirements that apply primarily to plant design and relocated them to 10 CFR Part 50. Conforming changes were made to 10 CFR Part 52 to reflect these changes.

As articulated in Regulatory Guide 4.7, "General Site Suitability Criteria for Nuclear Power Stations," which was revised in conjunction with the 1996 rule, both the exclusion area boundary described by 10 CFR 52.17(a)(1)(ix)(A) and the low population zone described by 10 CFR 52.17(a)(1)(ix)(B) (both of which are defined in 10 CFR 50.2) depend on site characteristics and aspects of the plant design. In effect, certain elements of siting and design have been inextricably linked and remain so.

Based on this regulatory history, the NRC continues to believe that dose consequence evaluation factors must be considered by ESP applicants as required by 10 CFR 52.17(a)(1). Requirements in 10 CFR Part 100, which are defined as the siting requirements for 10 CFR Part 52 applicants, must be met for the NRC to approve "a site for one or more nuclear power facilities separate from the filing of an application for a...combined license for such a facility" (§ 52.12), and therefore must be addressed at the ESP stage. While the meteorology is solely dependent on the site, the site atmospheric dispersion factors have a dependency on the design parameters (e.g., height of building cross-section for evaluation of the building wake effects) and the footprint of the plant (e.g., for determination of the distance of the release location to the exclusion area boundary). Therefore, the site atmospheric dispersion factor alone cannot be used to meet the criteria for radiological dose consequences of postulated accidents as required by Section 52.17(a)(1) because both site characteristics and design information are necessary in order to perform the required assessment. If an ESP applicant pursues the plant parameter envelope approach, the staff expects the application information to include the bounding reactor accident source terms, in addition to site atmospheric dispersion factor values, so that the staff can evaluate the acceptability of the site under the radiological consequence evaluation factors identified in 10 CFR 52.17(a)(1)(ix).

At the COL stage, an applicant referencing an ESP that used a plant parameter envelope approach would be required, in accordance with § 52.79(b), to provide information sufficient to demonstrate that the design of the facility falls within the site characteristics and bounding design parameters specified in the early site permit. Therefore, if the COL applicant can demonstrate that the characteristics of its actual facility design are bounded by the PPE values it postulated at the ESP stage, then no further analysis is necessary regarding compliance with Part 100.

The commenters suggested that the ESP approach for addressing compliance with Part 100 requirements should be similar to that used in the current rule to address emergency planning. Section 52.17(a)(1) requires ESP applicants to "identify physical characteristics of the proposed site ... that could pose a significant impediment to the development of emergency plans." The commenters stated that in that way, the rule recognizes that while emergency planning is an important consideration in determining site suitability, the ESP applicant may not be able to demonstrate compliance with Part 50, Appendix E, requirements at the ESP stage. Rather, the commenters asserted that the only requirement for ESP is to identify significant impediments to development of emergency plans, and if there are any, measures to mitigate or eliminate them.

The commenters noted that the proposed rule uses a similar approach to address adequate security plans. Proposed § 52.17(a)(1)(xi) requires ESP applicants to demonstrate that “site characteristics are such that adequate security plans and measures can be developed.”

The commenters stated that, like EP and security, radiation dose consequence criteria cannot be shown to be met at the ESP stage if the applicant has not selected a design and/or does not have the necessary design information available, such as information on systems, structures, components and source terms. The commenters stated that “such an ESP applicant could, however, demonstrate that radiation dose consequence criteria can be met by providing a sample analyses based on a typical plant design and site characteristic X/Q.” The commenters stated that this is similar to the approach used by the NRC staff and the first three applicants for ESP. The commenters noted that a COL applicant referencing such an ESP would be required to perform specific radiation dose consequence analyses for the specific design selected, and these analyses would be subject to NRC review.

The commenters suggested that if an ESP applicant has selected a design and has the necessary design information, the applicant may provide design-specific radiation dose consequence analyses, using the site characteristic X/Q. The commenters stated that once these analyses are approved in the ESP, compliance with Part 100 dose consequence criteria would be considered resolved for future applicants referencing the ESP, consistent with Section 52.39(a)(2), and these analyses would not be subject to further NRC review.

NRC Response: The NRC agrees that § 52.17(a)(1) should reflect the option for ESP applicants to use postulated design parameters in lieu of actual design information but notes that this allowance was provided for in the proposed rule. Specifically, § 52.17(a)(1)(i) states that the application must contain the specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used [emphasis added]. The NRC does not agree, however, that changes are needed to clarify the nature of radiological consequence analyses that are required of ESP applicants. This issue has been discussed with NEI in public meetings and in letters from the NRC dated February 5 and June 20, 2003 (ADAMS Accession Nos. ML030210341 and ML031150617), on the resolution of Early Site Permit Topic 7 (ESP-7), which involved guidance for satisfying 10 CFR 52.17(a)(1) requirements. The NRC staff also addressed the issue in SECY-03-0105, “Early Site Permit Application Readiness,” dated June 24, 2003, and in NRC’s August 4, 2003 letter to NEI providing the NRC’s responses to NEI’s comments on draft Review Standard (RS)-002, “Processing Applications for Early Site Permits,” Sections 15 and 17.1.1 (ADAMS Accession No. ML031920465). During all of these discussions, the NRC has consistently maintained that dose consequence evaluation factors must be considered in an ESP application as required by § 52.17(a)(1).

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Accident considerations historically have been of key importance in reactor siting. Major developments in risk assessment, such as the issuance of the Reactor Safety Study (WASH-

1400), and NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," as well as the occurrence of the Three Mile Island accident in 1979 and the accident at Unit 4 of the Chernobyl reactor in the Soviet Union in 1986, have heightened awareness, knowledge, and concerns in this area. Siting factors and criteria are important in assuring that radiological doses from normal operation and postulated accidents will be acceptably low. In 1996, the NRC amended its regulations to update the criteria used in decisions regarding power reactor siting (61 FR 65176; December 11, 1996). In that rulemaking, the NRC modified source terms and dose calculation requirements that apply primarily to plant design and relocated them to 10 CFR Part 50. Conforming changes were made to 10 CFR Part 52 to reflect these changes.

As articulated in Regulatory Guide 4.7, "General Site Suitability Criteria for Nuclear Power Stations," which was revised in conjunction with the 1996 rule, both the exclusion area boundary described by 10 CFR 52.17(a)(1)(ix)(A) and the low population zone described by 10 CFR 52.17(a)(1)(ix)(B) (both of which are defined in 10 CFR 50.2) depend on site characteristics and aspects of the plant design. In effect, certain elements of siting and design have been inextricably linked and remain so.

Based on this regulatory history, the NRC continues to believe that dose consequence evaluation factors must be considered by ESP applicants as required by 10 CFR 52.17(a)(1). Requirements in 10 CFR Part 100, which are defined as the siting requirements for 10 CFR Part 52 applicants, must be met for the NRC to approve "a site for one or more nuclear power facilities separate from the filing of an application for a...combined license for such a facility" (§ 52.12), and therefore must be addressed at the ESP stage. While the meteorology is solely dependent on the site, the site atmospheric dispersion factors have a dependency on the design parameters (e.g., height of building cross-section for evaluation of the building wake effects) and the footprint of the plant (e.g., for determination of the distance of the release location to the exclusion area boundary). Therefore, the site atmospheric dispersion factor alone cannot be used to meet the criteria for radiological dose consequences of postulated accidents as required by Section 52.17(a)(1) because both site characteristics and design information are necessary in order to perform the required assessment. If an ESP applicant pursues the plant parameter envelope approach, the staff expects the application information to include the bounding reactor accident source terms, in addition to site atmospheric dispersion factor values, so that the staff can evaluate the acceptability of the site under the radiological consequence evaluation factors identified in 10 CFR 52.17(a)(1)(ix).

At the COL stage, an applicant referencing an ESP that used a plant parameter envelope approach would be required, in accordance with § 52.79(b), to provide information sufficient to demonstrate that the design of the facility falls within the site characteristics and bounding design parameters specified in the early site permit. Therefore, if the COL applicant can demonstrate that the characteristics of its actual facility design are bounded by the PPE values it postulated at the ESP stage, then no further analysis is necessary regarding compliance with Part 100.

Comment 008-2: A commenter brought up the topic of combined permits and licenses but was not aware that any have been requested yet. The commenter stated that the site permit material includes design concepts, a plant parameter envelope, and pointed out that it is not apparent that the site approval applications were for a specific design like they were in the past.

The commenter asked when in the process the NRC plans to evaluate the specific design that a party wants to build so that the NRC can evaluate how the design copes with the environmental extremes, how the public is going to be protected from accidents, how the design can impact the environment, and what can be done to make the impact even smaller. The commenter asked if the NRC should instead require applicants to show the actual designs that they want to build on the sites they want approved instead of a concept. The commenter stated that, locally, industry cannot obtain a building permit until the architect's plans have been approved. Similarly, the commenter suggested that the NRC should not approve construction and operation until the actual design for the place on the site. The commenter also noted that it is not clear what value the envelope has in the rule, and questioned whether it can work years in advance of the actual decision to build something, and requested that it be defined to avoid "bait and switch."

NRC Response: The commenter is correct in that an early site permit applicant need not specify a particular design in its application. The regulations allow applicants to specify a range of designs that are under consideration. Such a range of designs can be described by using a "plant parameter envelope." When the early site permit is referenced in a combined license application, however, the combined license applicant must specify the specific design it intends to build at the site. The NRC only approves construction and operation of the facility when the combined license is issued, so, contrary to the commenters assertion, the NRC does not approve construction and operation until the actual design of the facility is known.

New Requirement for ESP Applicants to Provide ITAAC

Comment 007-16: Several commenters noted that proposed 10 CFR 52.17(b)(3) would require ESP applicants to provide inspections, tests, analyses, and acceptance criteria (ITAAC) on emergency planning (EP) for both major features or complete programs. The commenters also noted that proposed § 52.24(a)(5) would require a Commission finding that the ESP proposed ITAAC, "including any on emergency planning," are necessary and sufficient to make a reasonable assurance finding, and that the Supplementary Information for the proposed rule (71 FR 12789) explains the purpose of these proposed provisions. The commenters stated that an ESP applicant should not be required to propose EP ITAAC for major features of an EP plan.

The commenters noted that this discussion is inconsistent with proposed § 52.17(b)(3) in that it focuses solely on the need for EP ITAAC when the ESP application includes complete and integrated emergency plans. The commenters stated that the Supplementary Information does not identify the need for EP ITAAC when the ESP application includes only EP "major features." The commenters believe the Supplementary Information is correct and that EP ITAAC should not be required for the "major features" option. The commenters stated that the NRC does not need to make a reasonable assurance finding with respect to the description of "major features" of an EP plan submitted at the ESP stage. Instead, the commenters noted that under 10 CFR 52.18, the NRC is only required to determine that the major features are "acceptable." The commenters concluded that, using the staff's rationale, EP ITAAC are not necessary. The commenters noted that the first three ESPs each reflect use of the "major features" option and are progressing toward NRC approval without ITAAC on EP major features.

The commenters also stated that it may not be possible to develop ITAAC for EP major features at the ESP stage because, by definition, information on EP major features will not include details of the complete EP program. The commenters suggested that because in some cases it might be necessary to have those EP program details in order to develop appropriate EP ITAAC, development of EP ITAAC should be deferred to the COL stage when detailed EP program information will be available.

The commenters noted that in preliminary discussions between NRC and the commenters on this topic, it has been acknowledged that the existing language in Part 52 does not preclude any ESP applicant from proposing EP ITAAC. Given the possibility that EP ITAAC may in the future be determined to be practical and useful for ESP applicants using the “major features” option, the commenters would not object to adding a permissive provision to the end of Section 52.17(b)(3).

Finally, the commenters recommend that Section 52.24(a)(5) be modified to reflect that EP ITAAC are the only type of ITAAC envisioned for ESPs.

NRC Response: NRC agrees in part with the commenter. Specifically, the staff agrees with NEI that the ESP applicant should not be required to propose EP ITAAC for major features of an EP plan, and that 10 CFR 52.17(b)(3) should be modified to reflect the commenter’s proposed revision, including the permissive provision. The staff does not agree that the language “after [insert date of final rule]” should be added, as this is considered unnecessary because any ESP application with complete and integrated emergency plans must include some EP ITAAC, regardless of whether they are submitted prior to or after the effective date of this rulemaking. While the current rules do not require EP ITAAC for complete and integrate emergency plans in an ESP application, a reasonable assurance determination can not be made without them. Further, the current rules do not preclude submission of ESP EP ITAAC for complete and integrated emergency plans. Thus, the effective date of the rulemaking requirement for ESP EP ITAAC for complete and integrated plans is inconsequential, as it relates to the NRC (and DHS) reasonable assurance determination. Further, the staff does not agree that 10 CFR 52.24(a)(5) should be modified to reflect that EP ITAAC are the only type of ITAAC envisioned for ESPs. The staff believes that the existing language provides additional flexibility for ESP applicants, in that they would be allowed to propose ITAAC for areas other than emergency planning, if they so desire.

New Requirement for ESP Applicants to Address Construction Impacts on Existing Plants

Comment 007-20: Several commenters noted that proposed 10 CFR 52.17(a)(1)(x) would require ESP applicants to address impacts on operating units of constructing new units on existing sites. The commenters stated that this provision in the proposed rule is contrary to the industry-NRC understanding on this matter, as documented in correspondence in 2003 regarding ESP Topic ESP-19 (see NEI Letter dated May 14, 2003, and NRC Letter dated August 11, 2003). The commenters noted that, as discussed by the NRC at the workshop on March 14, 2006 (Tr. 78-79), NRC apparently did not consider ESP-19 when it prepared the proposed rule, and it does not know why it changed its position. The commenters believe that the requirement proposed in § 52.17(a)(1)(x) is both unnecessary and potentially impossible for an ESP applicant to implement, and suggested that therefore, this provision should be deleted.

The commenters stated that, consistent with the resolution of ESP-19, the COL applicant (and not the ESP applicant) should have the obligation to identify the impacts of construction on existing operating plants. The commenters stated that the COL applicant is in the best position to provide such information, since it will have final information regarding the design and construction plans. In contrast, the commenters stated that the ESP applicant will not have final design information or construction plans. Therefore, the commenters stated that it will be difficult, if not impossible, for an ESP applicant to provide the information specified in the proposed rule. The commenters also stated that in any event, the issue does not relate to site suitability.

The commenters noted that proposed 10 CFR 52.79(a)(31) includes a requirement for a COL applicant to include such information in the COL application on construction impacts, and that provision reflects the current requirements in 10 CFR 50.34(a)(11). The commenters state that this approach also is consistent with the staff's comments in its December 27, 2005, response to the Commission's SRM. Therefore, the commenters concluded that there is no need to impose this requirement on ESP applicants.

Comment 012-9: A commenter stated that they are concerned that the proposed rule would unnecessarily expand the safety review in an ESP proceeding. The commenter stated that proposed § 52.17(a)(1)(x) would expand the safety review in an ESP proceeding to include an evaluation of the potential hazards to operating units from construction activities, as well as a description of the managerial and administrative controls to be used to assure that the limiting conditions of operation for existing units will not be exceeded. The commenter asserted that this proposal would make the ESP process more burdensome without any commensurate safety benefit.

The commenter noted that under the current regulations, the requirement to evaluate the potential hazards to operating units from construction activities applies only at the COL stage. The commenter stated that the current requirement in 10 CFR 50.34(a)(11) is not one of the requirements incorporated into 10 CFR § 52.17(a)(1) and therefore does not apply to an ESP application. The commenter noted that in a letter dated August 11, 2003 to NEI, the NRC stated, "The NRC staff agrees that the requirements of 10 CFR § 50.34(a)(1) are not applicable to an ESP application."

The commenter stated that the NRC now proposes to make this evaluation a new requirement for ESP applicants "so that all applicable issues are included in the NRC's review of site suitability. . ." [See 71 FR 12790] The commenter asserted that the proposed evaluation and requirement to establish managerial and administrative controls go far beyond any review that is needed to determine the suitability of the site. The commenter suggested that at most, any consideration of this issue should be limited to whether the presence of the existing units would preclude the construction of additional units. The commenter stated that because construction has been performed without problem at many operating units, the only question should be whether there are any unique characteristics of site or existing units that would pose any insurmountable impediment to constructing new units.

The commenter stated that as a practical matter, information may not exist at the ESP stage to perform a specific evaluation of the potential hazards from construction, because the design and footprint of the new units may not be known. The commenter further stated that the

evaluation may be premature, because construction may not occur for many years. The commenter noted that an ESP remains valid for 20 years and may be renewed.

The commenter stated that a safety review is not needed for those preconstruction activities that an ESP holder may perform pursuant to 10 CFR 52.25(a). The commenter noted that such a review is not required in order to authorize these preconstruction activities under 10 CFR 50.10(e), and therefore should not be required for an ESP. The commenter stated that the NRC staff has acknowledged that an “ESP does not authorize construction activities that could pose safety/security issue[s] to existing operating units onsite.” [See Attachment to Memorandum from EDO to Commissioners, “Response to Staff Requirements Memorandum” (Dec. 27, 2005)] The commenter added that moreover, administrative controls already exist at any site on which reactors are already operating. The commenter stated that a licensee for an operating unit has the authority to determine all activities in the exclusion area. [See 10 CFR 100.3.] The commenter noted that in addition, the licensee is required by 10 CFR 50.59 to evaluate changes to its facility. The commenter stated that proposed construction activities would also be evaluated by the licensee for operating units under its site access and security programs. The commenter asserted that there is, therefore, simply no need for these proposed new requirements.

NRC Response: The NRC agrees that proposed § 52.17(a)(1)(x) was contrary to the industry-NRC understanding on this matter, as documented in correspondence in 2003 regarding ESP Topic ESP-19 (see NEI Letter dated May 14, 2003 (ML031920246), and NRC Letter dated August 11, 2003 (ML031490478)) and that the COL applicant is in the best position to provide such information, since it will have final information regarding the design and construction plans. The NRC is considering whether to include a condition in early site permits that would require the permit holder to notify the operating plant licensee prior to conducting any activities authorized under § 52.25. These controls should be sufficient to evaluate construction activities at a site with an existing operating unit and the NRC has deleted this provision from subpart A in the final rule. COL applicants will, however, continue to be required to meet this provision under § 52.79(a)(31).

Delayed response by an ESP holder to information requests

Comment 007-31: Several commenters noted that proposed § 52.39(e) would allow the NRC to request information from an ESP holder if the staff first evaluates the burden to be imposed “in view of the potential safety significance of the issue to be addressed in the requested information,” and if the evaluation conforms to 10 CFR 50.54(f). The commenters also noted that the proposed new provision also states that such an evaluation is not necessary if the request seeks to verify compliance with the current licensing basis of the ESP. The commenters stated that the proposed rule should be modified to allow the ESP holder to defer a response to NRC questions until the COL proceeding or until the ESP holder submits a request for renewal of the ESP. The commenters stated that such an allowance is appropriate for several reasons: (1) an ESP holder will not necessarily maintain (and should not be required to maintain) a technical staff to respond to information requests from the NRC, and therefore, an ESP holder may not be able to submit an appropriate response until the COL proceeding application or until the ESP holder submits a request for renewal of the ESP; (2) an ESP holder is not allowed to perform any safety-related construction activities, therefore, there will be no adverse impact upon safety if the ESP holder is allowed to defer a response to an NRC request

for information; and (3) an ESP holder may never submit a COL application. The commenter concluded that in such an event, the NRC's request for information would be moot.

NRC Response: The NRC does not agree with the commenters that the proposed rule should be modified to allow the ESP holder to defer a response to NRC questions until the COL proceeding or until the ESP holder submits a request for renewal of the ESP. The commenters claimed that an ESP holder will not necessarily maintain (and should not be required to maintain) a technical staff to respond to information requests from the NRC. An ESP holder, like any other licensee, is required under § 50.71(a) to "maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations, and orders of the Commission in effectuating the purposes of the Act, including Section 105 of the Act, and the Energy Reorganization Act of 1974, as amended." Section 50.71(c) requires that "records that are required by the regulations in this part or Part 52 of this chapter, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification." Therefore, it is the ESP holder's responsibility, as it is every licensee's responsibility, to have staff to maintain records and respond to any inquiries from the NRC in a timely fashion.

New Requirements for an ESP Applicant to Evaluate its Application Against the Standard Review Plan (SRP)

Comment 007-39: Several commenters noted that proposed § 52.17(a)(1)(xiii) would require an ESP application to include an evaluation of the site against applicable sections of the Standard Review Plan (SRP) revision that was in effect 6 months prior to the docket date of the application. The commenters noted that the NRC issued RS-002, Processing Applications for Early Site Permits, as guidance for ESP application review. The commenters recommended that the final Part 52 rule should have flexibility to allow an ESP application to provide an evaluation against RS-002 or other NRC applicable guidance documents, in lieu of an evaluation against the SRP.

NRC Response: The NRC does not agree with the commenters' recommendation that the final Part 52 rule should have flexibility to allow an ESP application to provide an evaluation against RS-002 or other NRC applicable guidance documents, in lieu of an evaluation against the SRP. The NRC plans to have the current SRP revision finalized by March 31, 2007. At that time, the majority of the contents of RS-002 will be replaced with information indicating the SRP sections that are applicable to NRC review of an ESP.

Deletion of Provision that an ESP is a "Partial Construction Permit"

Comment 007-44: Several commenters noted that the proposed rule would delete the statement in 10 CFR 52.21 that an ESP is a "partial construction permit." The commenters stated that the Supplementary Information for the proposed rule does not explain the purpose, intent, or effect of deleting this provision in the current rule. The commenters also noted that, despite the deletion in the rule language, the NRC continues to refer to an ESP as a partial construction permit at various places throughout the NOPR (see 71 FR 12790, 12791, 12809, 12812, and 12815). The commenters stated that therefore, the NOPR is not internally consistent, and it is unclear whether the Commission intends for the deletion to have any substantive effect.

The commenters believe that the proposed change would remove some clarity afforded by the current rule. The commenters stated that this proposed deletion could result in certain benefits being removed from the ESP, since it would no longer have the status of a partial construction permit. Furthermore, the commenters stated that the existing provision is useful, and there is no reason why an ESP should not continue to be referred to as a partial construction permit.

NRC Response: The NRC does not agree with the commenter that it is necessary to re-instate the referenced provision in current § 52.21. That provision states that, "An early site permit is a partial construction permit and is therefore subject to all procedural requirements in 10 CFR Part 2 which are applicable to construction permits." Although the NRC continues to view an ESP as a partial construction permit, the NRC does not believe it is necessary to state so in the rule. One of the main goals of this rulemaking is to make conforming changes throughout 10 CFR so that all of the related regulations contain specific requirements for Part 52 licenses, certifications, and approvals. In doing so, the NRC has removed the need to couch Part 52 requirements in terms of their relation to requirements for construction permits and operating licenses. For example, Part 2 has been revised to explicitly address ESPs, so there is no need to state that an ESP is a partial construction permit subject to requirements applicable to construction permits. However, because the NRC did not intend any substantive effect by its removal of the language referring to ESPs as a partial construction permit, other than to indicate that the entire body of NRC regulations now contain requirements specific to ESPs, it is revising the definition of an ESP in § 52.1 to include a statement that an ESP is a partial construction permit, in deference to the commenters. The NRC believes that § 52.1 is a more appropriate location for such a statement. Placing the statement in the ESP definition is consistent with the NRC definition of a COL, wherein that definition states that a COL is a combined construction permit and operating license with conditions.

The Proposed Rule Would Allow the NRC Arbitrarily to Withhold the Issuance of an ESP

Comment 007-45: Several commenters noted that proposed § 52.24(a) states that the Commission *may* issue an ESP if it makes the requisite findings. In contrast, the commenters noted that the current rule states that the Commission *shall* issue the ESP if it makes the requisite findings. The commenters stated that the Supplementary Information for the proposed rule provides no explanation or justification for this proposed amendment. The commenters stated that the proposed provision would enable the NRC arbitrarily to withhold issuance of an ESP, even though the ESP application has satisfied all applicable requirements. The commenters stated that the NRC should be required to issue the ESP in such cases.

NRC Response: The Commission disagrees with the commenter's legal analysis, to the extent that it suggests that the Commission's use of the term, "may," affords the Commission to legal authority to act arbitrarily and capriciously in withholding an ESP. No administrative agency has the authority to act in derogation of the Administrative Procedure Act and applicable federal caselaw - much less the authority to adopt a regulation which effectively grants itself dispensation from compliance with applicable law. The Commission regards the use of the term, "may," as consistent with and in furtherance of the AEA's direction that licenses shall not be issued if the Commission believes that issuance of the license would be "inimical to the common defense and security or to the health and safety of the public." AEA, Section 103.e. as the Commission has stated on other occasions, compliance with the Commission's regulations are merely presumptive of adequate protection to public health and safety and common

defense and security. See 53 FR 41178, 41179-80 (October 20, 1988); 50 FR 20603, 20609 (June 6, 1988).³ There may be circumstances where an safety issue has been identified but has yet to be addressed through rulemaking. In such cases, the Commission may, under the authority of Section 103.e., lawfully decline to issue the license, or issue the license with conditions addressing the safety issue, despite the applicant having demonstrated compliance with all relevant Commission regulations. The use of the term, “may,” reflects the Commission’s authority in this regard, and avoids the need for the Commission in this circumstance to issue itself a dispensation from compliance with its own regulation.

Moreover, the commenter does not address other Commission regulations governing issuance of reactor licenses that uses the term “may,” e.g., § 54.29 (renewed operating licenses under Part 54; Part 52, Appendix M, paragraph 10 (manufacturing licenses for nuclear power plants), which would appear to suffer the same “defect” complained of by the commenter. The commenter also does not appear to recognize that the Commission proposes to standardize on the term, “may,” throughout Part 52, see § 52.54(a)(standard design certification); and § 52.97(a)(1)(combined license). The Commission does not regard any of these regulations as authorizing arbitrary and capricious action by the Commission in the issuance of licenses.

In sum, the use of the term, “may” affords the Commission the authority to deny issuance of a license despite a finding of compliance with the Commission’s regulations, if the Commission has identified either a public health and safety or common defense and security issue not addressed by its regulations. Accordingly, the Commission declines to adopt the commenter’s suggested change to § 52.24(a), and no change to any part of the final rule has been made as the result of the comment.

The Proposed Rule Would Allow Litigation of Changes to ESP Emergency Planning Information That Are Not Significant to Safety

Comments 007-46: Several commenters noted that proposed 10 CFR 52.39(c)(1)(iv) would allow litigation in a COL proceeding referencing an ESP contentions on “new or additional information” provided in the COL application “which materially affects the Commission’s earlier determination on emergency preparedness” in the ESP proceeding, or “is needed to correct inaccuracies in the emergency preparedness information approved in the early site permit.” The commenters stated that this proposed provision identifies a different standard for emergency planning contentions than that in 10 CFR 50.54(q). The commenters noted that § 50.54(q) allows a licensee to make changes in an NRC-approved emergency plan, without prior NRC approval, if the change does not decrease the effectiveness of the plan and the plan as changed continues to meet the requirements in Appendix E to Part 50. The commenters stated that this standard ensures adequate protection of safety, and has been accepted and used by the industry and NRC for years. The commenters stated that this same standard should be applied to changes in emergency plans approved by the NRC in the ESP proceeding, and that the NRC has not explained the basis for or justified the higher standard in the proposed rule.

³NRC staff actions have been consistent with this principle, see, e.g., *FirstEnergy Nuclear Operating Company* (Davis-Besse Nuclear Power Station, Unit 1), Directors Decision DD-04-1, 59 NRC 215, 221 (2004).

The commenters stated that proposed § 52.39(c)(1)(iv) is objectionable because it is inconsistent with proposed § 52.39(a)(2). The commenters noted that § 52.39(a)(2) states that, “if the early site permit approved an emergency plan (or major features thereof) that are in use by a licensee of a nuclear power plant, the Commission shall treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee’s emergency plans in compliance with § 50.54(q) of this chapter occurring after issuance of the early site permit.” The commenters concluded that therefore, proposed § 52.39(c)(1)(iv) would appear to allow intervenors to raise contentions on material changes that have “finality” under proposed § 52.39(a)(2), which is inconsistent with the concept of finality.

The commenters contended that, even more fundamentally, there is no reason for the NRC to distinguish between approved emergency plans for ESPs for existing reactor sites and approved emergency plans for ESPs on greenfield sites. The commenters stated that as long as the emergency planning information has been approved by the NRC in the ESP proceeding, it should be afforded the same protection whether or not the emergency plan is the same as that being used by an existing plant. The commenters concluded that therefore, all changes to approved emergency planning information should be judged under the standards in § 50.54(q), not just those changes related to sites with an existing nuclear plant.

The commenters also stated that the “materiality” standard in proposed § 52.39(c)(1)(iv) could allow litigation of changes that are not significant to safety. The commenters asserted that, in this regard, the NRC has typically defined “material” as information that has the ability to influence the agency in the conduct of its regulatory responsibilities [See Virginia Elec. and Power Co. (North Anna Power Station, Units 1 and 2), CLI-76-22, 4 NRC 480 (1976) North Anna, CLI-76-22, 4 NRC at 486 and at 491.] The commenters stated that under this definition, a change in emergency planning information may be material, but may not represent a decrease in safety, and that if a change does not adversely affect safety, it should not be subject to NRC approval or hearings.

The commenters suggested that in this regard, it is possible that the proposed rule is defining the term “material” in a manner that is different from the NRC’s traditional definition. The commenters noted that the Supplemental Information for the proposed rule (71 FR 12795) includes the discussion regarding material changes in emergency planning.

NRC Response: The NRC agrees with the commenter in part and has made changes to § 52.39 in the final rule to address this issue. Specifically, the NRC revised § 52.39(a)(2) to add a provision that would provide a COL applicant referencing an ESP that had approved emergency plans that were not in use by a licensee of a nuclear power plant with finality for changes that are equivalent to those that could be made under § 50.54(q) without prior NRC approval had the emergency plan been in use by a licensee. The NRC agrees that this standard ensures adequate protection of safety, and has been accepted and used by the industry and NRC and that it is appropriate to apply this same standard to changes in emergency plans approved by the NRC in the ESP proceeding.

The NRC has also revised § 52.39(c)(iv) as suggested by the commenters to state that contentions may be litigated on matters related to new or additional information provided in the application that substantially alters the bases for a previous NRC conclusion and constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to

emergency preparedness. Since the final rule language suggested by the commenters is the definition that the NRC gave for information that could “materially affect” the Commission’s earlier decision, as indicated in the Supplementary Information section of the proposed rule, the NRC does not object to using this language in the rule itself. The NRC has decided to drop the language that referred to information “needed to correct inaccuracies” because, the language, by itself, could have allowed litigation of issues not significant to safety. The NRC believes that the final rule language encompasses all significant emergency preparedness matters that should be subject to litigation.

Inconsistent Treatment of ESPs

Comment 007-65: Several commenters noted that Proposed § 52.39(d) states that a “variance will not be issued once the construction permit, operating license, or combined license is issued.” The commenters stated that in contrast, proposed § 52.27(b)(2) indicates the ESP continues to be valid “in any hearing held under 10 CFR 52.103 before operation begins under a combined license which references the early site permit.” The commenters stated that proposed § 52.39 appears to be based on the presumption that the ESP will be subsumed into the construction permit (CP) or COL. The commenters stated that such a presumption is inconsistent with the proposed § 52.27. The commenters stated that if the ESP remains valid, then NRC regulations should contain a provision that allows for a request for a variance. The commenters went on to state that if the ESP is subsumed into the CP or COL, then no variance is necessary, but the ESP should not be valid during § 52.103 hearings.

The commenters recommended that Part 52 be revised so that an ESP is subsumed within a CP or COL once the latter is issued. The commenters stated that therefore, any terms or conditions (including ITAAC) in the ESP that cannot be resolved during the CP or COL proceeding would need to be included as terms and conditions in the CP or COL. The commenters continued that in addition, Part 52 should allow for cases in which an ESP has a broader scope than the CP or COL. The commenters gave as an example that if the ESP applies to two units but the CP or COL only applies to one unit, the ESP should remain in effect for the balance of the units not encompassed within the CP or COL.

NRC Response: The NRC agrees with the commenters that the language in §§ 52.27(b) and 52.39(d) is inconsistent. It is the NRC’s intention that the ESP be subsumed into the CP or COL once the CP or COL is issued. The NRC agrees that proposed § 52.27(b)(2) should be deleted and it has done so in the final rule. The NRC also agrees with the commenters’ suggestion that a new § 52.27(d) should be added in the final rule to clarify that, upon issuance of an application for a CP or COL that references an ESP, the ESP is no longer effective with respect to that CP or COL. However, the NRC believes it provides greater clarity to say that, upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license. The NRC does not agree that a statement needs to be included in the new § 52.27(d) that states that any terms or conditions in the ESP that could not be satisfied by the time of issuance of the CP or COL shall become terms or conditions of the CP or COL. This is because this statement is being added to § 52.24(b) in the final rule. The NRC believes it is more appropriate to address this issue in the “issuance” section of Subpart A rather than in the “duration” section of Subpart A.

Beneficial Changes Proposed for Part 52

Comment 007-75: Several commenters stated that the industry considers the changes in the NOPR in § 52.17(a)(1)(i), regarding the addition of the phrase, “or range of possible facilities;” and in § 52.39(a)(1), and § 52.39(c)(1)(i)-(iii) and (v), regarding the finality of ESP determinations, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

Transfer of an ESP

Comment 012-3: A commenter noted that the NRC proposes to add a new § 52.28 providing that transfer of an ESP will be processed under 10 C.F.R. § 50.80. The commenter does not object to this provision but recommends that the Commission should clarify when transfer of an ESP is necessary.

In particular, the commenter stated that the Commission should clarify that a COL applicant will remain able to reference an ESP held by another entity without any need for a transfer of the ESP. The commenter noted that under the current regulations, a COL may reference an ESP without regard to whether the COL applicant and the ESP holder are identical. [See, e.g., 10 CFR § 52.73.] The commenter continued to state that the ability of a COL applicant to reference an ESP held by another entity is clearly intended by the current rules. The commenter noted as an example that 10 CFR 52.25(a) provides that if an ESP contains a Site Redress Plan, “the holder of the permit, or the applicant for a construction permit or combined license who references the permit” may perform certain preconstruction activities. The commenter stated that if an ESP could only be referenced by its holder, the words quoted above would be meaningless, and it is axiomatic that laws must always be interpreted so as to give meaning to all words. [See, e.g., *Private Fuel Storage, LLC, (Independent Spent Fuel Storage Installation)*, CLI-02-29, 56 NRC 390, 397-98 & n.27 (2002). See also *United States v. Alaska*, 521 US 1, 59 (1997); *Rosenberg v. XM Ventures*, 274 F.3d 137, 141 (3d Cir. 2001).] The commenter continued to state that it makes sense that a COL holder should be able to reference an ESP held by another entity, because an ESP is essentially only a site suitability determination.

The commenter asserted that allowing this flexibility is very important to efficient proceedings, because it is possible that state approvals shortly before or after a COL filing could result in some entity other than the ESP holder being chosen to become the COL applicant. The commenter noted as an example that an ESP might be held by a regulated utility, but subsequent deregulation might require divestiture of generating capacity and result in some other entity submitting the COL application. The commenter noted that state approvals for a certificate of need might result in a change in the entity to construct and operate a plant, and construction financing requirements could also dictate the choice. The commenter suggested that if an ESP had to be transferred to accommodate such changes, the filing of a COL application might be unnecessarily delayed, or if already filed, the review of the COL might be disrupted.

The commenter noted that the NRC previously stated that they “would not permit a license applicant to reference an early site permit which it does not hold (or has rights to the permit contingent upon a NRC decision to issue a license whose application references the early site permit). To otherwise permit referencing of an early site permit by a non-holder would destroy the commercial value of the permit, and would prevent any entity from seeking an early site permit. This would frustrate the Commission’s regulatory objective of providing early regulatory approval of siting, emergency preparedness, and environmental matters.” [68 FR 40026, 40037 n.2, July 3, 2003] The commenter stated that, while the first sentence quoted above is not clearly worded, the commenter understands it to mean that a COL applicant may reference an ESP held by another entity if the ESP holder has given it the right to do so. The commenter stated that where a COL applicant and the ESP holder are affiliates, and the ESP holder has permitted the COL applicant to reference the ESP, the commercial value of the ESP would not be destroyed. The commenter asserted that consequently, a transfer of the ESP is unnecessary and all that should be required is a showing in the COL application that the ESP holder has consented to the reference of its permit.

Accordingly, the commenter recommended that in the Supplemental Information accompanying any final rule, the Commission should explain that the section governing transfers of ESPs does not signify that only an ESP holder may reference an ESP. Rather, the commenter suggested that transfer of an ESP is only necessary when responsibility for amending or renewing the permit changes. [See, e.g., 10 CFR 52.29(a) (“... the permit holder may apply for a renewal of the permit.”).]

NRC Response: The NRC disagrees with commenters’ suggestion that the statement of considerations clarify when a transfer of an ESP is necessary. The Commission’s revision to § 50.80 is a conforming change to a procedural regulation regarding the process by which the NRC processes and determines a transfer of a license. Section 50.80 does not, by itself, specify the circumstances for which a license transfer is necessary; it simply addresses what procedures must be followed if a license transfer request is received. Therefore, the Commission does not believe that it is necessary or desirable to provide such guidance in the context of this rulemaking.

New Requirements for Preconstruction Activity Authorization

Comments 012-4 and 013-1: Several commenters stated that their organizations are concerned that certain provisions of the proposed rule would make preconstruction work a licensed activity. The commenters respectfully submitted that these changes are unnecessary, would institute new standards and requirements for early site permitting, and would be bureaucratic and burdensome. The commenters noted that under the current rules in 10 CFR 52.25(a), an ESP holder may perform certain preconstruction activities if it has provided a site redress plan and if the NRC’s EIS prepared for the permit has concluded that the activities will not result in any significant environmental impact which cannot be redressed. The commenters stated that therefore, no specific authorization is currently required. The commenters noted that the proposed rule would delete this provision, and would allow preconstruction activities only if and to the extent specifically authorized in an ESP. [See 71 FR 12892 (proposed Section 52.24(c))]

The commenters stated that these changes are inappropriate for a number of reasons. First, the commenters stated that they elevate preconstruction work to a licensed activity. The commenters asserted that this is inconsistent with the original intent of the NRC rules, which was to designate those activities that did not require a construction permit.

The commenters noted that 10 CFR 50.10(b), promulgated in 1960, excluded site excavation, preparation of the site for construction, construction of roadways, railroad spurs, and transmission lines, and construction of non-nuclear facilities and temporary buildings from the definition of construction. [See 25 FR 8172, 1960] In 1968, driving of piles was added to the list of activities that could be performed without a construction permit. [See 33 FR 2381, 1968] The commenters noted that after the promulgation of NEPA, the NRC added 10 CFR 50.10(c) to provide for environmental review prior to “commencement of construction,” which it redefined. [See 37 FR 5745, 1972] The commenters also noted that the Commission later amended its rules again to allow the NRC staff to authorize limited work, including authorization to perform the activities in 10 CFR 50.10(e)(1), after completion of the hearings on NEPA and site suitability issues. The commenters noted that in the rule promulgating those changes, the Commission explained its position on this issue. [See 39 FR 14506, 14507, 1974]

The commenters stated that consequently, the activities specified in 10 CFR 50.10(e)(1), which are the activities that an ESP holder is permitted to perform by rule under 10 CFR 52.25(a), are not activities that must be licensed under the Atomic Energy Act. The commenters asserted that, as evidenced by 10 CFR 50.10(b), they do not have to be authorized by a construction permit (and therefore also do not have to be authorized by an ESP). The commenters stated that what the NRC rules are intended to do is to ensure that such activities are not performed prior to completion of the NEPA review, and where an ESP has been issued, that is obviously the case.

The commenters stated that it is not necessary to specify such activities in order to define the work that an ESP holder may perform. The commenters noted that under the current rules in 10 CFR 52.25(a), an ESP holder may only perform preconstruction activities that have been evaluated in the NEPA EIS and determined to involve no significant environmental impact that cannot be redressed. The commenters stated that therefore, the final EIS defines the scope of activities that may be performed under the rules. If an ESP applicant does not want authority under 10 CFR 52.25(a) to perform certain activities within the scope of 10 CFR 50.10(e)(1), it can exclude such activities from the scope evaluated in its application, and the NRC staff would then not evaluate the impacts of such activities in its EIS.

One of the commenters also stated that pre-construction activities currently outlined in 10 CFR 50.10(b) and 50.10(e)(1) should be authorized without the need for a prior permit or LWA. NRC approval of pre-construction activities should focus solely on matters pertaining to safety.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to these comments.

New Requirements for Preconstruction Activity Authorization

Comment 012-5: A commenter asserted that elevating the preconstruction activities to ones that can only be performed if authorized by a license creates a scheme that is more bureaucratic and limiting than the procedures not only under the current Part 52 rules, but also under the old Part 50 provisions. The commenter stated that this creates numerous undesirable consequences. The commenter noted as an example that under the existing rules in 10 CFR 52.25(a), preconstruction activities may be performed either by an ESP holder or by an applicant for a COL referencing an ESP (i.e., the ESP holder and COL applicant do not have to be the same entity). The commenter asserted that by requiring a specific authorization in the ESP and by deleting 10 CFR 52.25(a), the proposed rule would eliminate this flexibility.

NRC Response: The Commission disagrees with this comment. Under the former provisions of 52.17 and 52.22, the early site permit would itself authorize the LWA activities described in § 50.10(e)(1). The Commission does not see how the provisions in the March 2006 reduced the flexibility of either the early site permit holder or the combined license applicant. In any event, after consideration of public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The Commission believes that the commenter's concerns have been largely rendered moot by these changes.

New Requirements for Preconstruction Activity Authorization

Comment 012-6: A commenter stated that the proposal to require specific authorizations in the rule for preconstruction activities changes the fundamental nature of the ESP from a site suitability determination to one that authorizes activities, and thus implicates certification requirements under the Clean Water Act (CWA) and the Coastal Zone Management Act (CZMA). The commenter noted that Section 401 of the CWA prohibits the NRC from issuing a license to conduct an activity that may result in a discharge into navigable waters unless the state certifies that the discharge complies with certain requirements under the Act or waives certification. [See 33 USC Section 1341(a).] The commenter also noted that Section 307 of the CZMA requires, for any federal license to conduct an activity affecting a coastal zone, a certification that the activity complies with the enforceable policies of the state's Coastal Zone Management Program. [See 16 USC Section 1456(c)(3).] The commenter stated that under the current regulations, preconstruction activities are activities that do not have to be licensed, and therefore these certification requirements should be inapplicable. This does not mean that state review is avoided. Construction runoff is a point source discharge requiring a National Pollutant Discharge Elimination System permit from the state. However, this permitting would occur when the company proposing to build a new plant is ready to commence preconstruction activities, rather than at the ESP stage when such review may be premature. The commenter stated that under the proposed rule, either certifications or waivers would have to be obtained from the state, which can be very difficult when the schedule for preconstruction activities is unknown (as is the case for an ESP which remains in effect for 20 years).

NRC Response: The Commission disagrees with this comment. An applicant for an ESP under former § 52.17 could request the authority to conduct the LWA activities described in § 50.10(e)(1), which were considered, under the provisions of the former rule, to be construction activities. Hence, as other commenters recognize, NRC permission in the form of

an ESP specifically authorizing such activities is required. To the extent that the commenter is arguing that the NRC should not consider these activities to be construction and therefore should not require NRC approval, the NRC agrees. This determination is reflected in the substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule.

New Requirements for Preconstruction Activity Authorization

Comment 012-7: A commenter stated that by turning preconstruction work into a licensed activity under the Atomic Energy Act, the proposed rule also adds new technical qualification requirements. The commenter noted that in particular, the proposed rule would amend the findings that the Commission must make for issuance of an ESP to include a finding that “the applicant is technically qualified to engage in any activities authorized.” [See 71 FR 12892, proposed § 52.24(a)(4)] The commenter stated that such a requirement does not exist under the current rules, and indeed, preconstruction activities have never required such a finding. The commenter also stated that there are no applicable standards or guidance. The commenter asserted that it is anomalous to require technical qualifications for the activities currently permitted by 10 CFR 52.25(a), because no construction of safety-related structures is permitted.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to this comment .

New Requirements for Preconstruction Activity Authorization

Comment 012-8: A commenter noted that the proposed rule would require the proposed preconstruction activities to be identified and described in the site safety analysis report (SSAR). [See 71 FR 12891, proposed § 52.17(c)] The commenter noted that the rulemaking notice explains that this new section of the SSAR “would enable the NRC staff to perform its review of the request, consistent with past practice, to determine if the requested activities are acceptable under 10 CFR 50.10(e)(1).” [See 71 FR 12791] The commenter stated that alternately, 10 CFR 50.10(e)(1) allows these activities to be authorized if the staff has completed its EIS and if the Licensing Board has made its NEPA and site suitability findings. The commenter stated that there is no requirement for an NRC safety review in § 50.10(e)(1), and therefore there is no basis for the current proposal to require preconstruction activities to be discussed in the SSAR. The commenter asserted that, to the extent that the proposed rule may be intimidating that some additional safety review should be performed, without any specified standards or guidance, it would make the new licensing process more burdensome. It is possible that the NRC staff may be contemplating a review of preconstruction activities to evaluate potential impacts on existing units at multi-unit sites. As discussed in the next section, the licensees of existing units have authority, programs and procedures necessary to maintain safety and security at these sites, and the NRC staff has acknowledged that the preconstruction activities would not pose safety and security issues.

The commenter stated that rather than making the new licensing process more efficient and effective, these provisions would institute new standards, reviews, and approvals on to the process. The commenter recommended that if the NRC does proceed with the promulgation of these changes, it should apply such changes only to ESPs applied for after the effective date of the new rule. The commenter stated that the current 10 CFR 52.25 should remain in effect and applicable to the ESPs already applied for.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to these comments.

New Requirements Related to Limited Work Authorizations

Comment 007-30: Several commenters stated that the proposed rule contains new requirements that place unnecessary new limits and burdens on COL applicants and ESP holders that wish to obtain Limited Work Authorizations (LWAs) and perform pre-construction site preparation activities. The commenters suggested that there may be situations in which the ESP holder did not include a site redress plan in its ESP application. The commenters stated that if, as they proposed in their May 25, 2006, partial comments (comment letter 004), NRC determines that future applicants need not obtain NRC authorization to perform LWA-1 activities, then this omission will become moot or cease to be significant.

One commenter added that the changes proposed in the May 25, 2006, letter on preconstruction activities/LWAs are very important to the commenter because they could accelerate a plant's construction completion date by more than a year. The commenter clarified that specifically, existing constraints on pre-construction activities that are not safety-related (LWA-1 activities) are not required by existing statutes. The commenter stated that therefore, LWA-1 activities should not require NRC authorization. The commenter also stated that the authorization of certain limited pre-construction activities that have a nexus to nuclear safety (LWA-2 activities) should not have to await the issuance of a final environmental impact statement (EIS).

The commenters went on to suggest that alternatively, if the Commission determines that a site redress plan continues to be a prerequisite for LWA-1 and LWA-2 activities, the NRC should revise its regulations to authorize ESP holders (including those whose ESP applications were under review at the time the final rule becomes effective) the flexibility to submit a site redress plan if they did not do so originally, so that they may conduct LWA activities.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to these comments.

5.3.3 Subpart B – Design Certification

Terminology

Comment 001-1: A commenter noted that throughout 71 FR 12782 the terms “transients,” “transient conditions,” “limiting transient,” “operational transients” are used to mean “anticipated operational occurrences.” The commenter stated that, with the exception of the term “Anticipated Transients Without Scram,” no other “transient” term is defined in 10 CFR or the standard review plan. The commenter indicated that 10 CFR Part 50, Appendix A, does specifically define “anticipated operational occurrences,” and the general design criteria correctly refer to “anticipated operational occurrences.” The commenter suggested that to assure consistency throughout the regulation, the Statements of Consideration, and Appendix A, (except for anticipated transients without scram) all “transient” terms should be changed to “anticipated operational occurrences.”

NRC Response: Revising the term “transient” throughout Part 50 is not within the scope of the Part 52 rulemaking. No changes have been made to Part 50 as a result of this comment.

Comment 001-2: One commenter pointed out that proposed § 52.47(a)(16) applies “SSCs important to safety” to Part 50, Appendix S, but Appendix S applies to safety-related SSCs, not all SSCs important to safety. Thus, the term “SSCs important to safety” should be replaced with “safety-related SSCs.”

NRC Response: The NRC agrees with the comment, and has modified the language in § 52.47(a)(20) in the final rule.

Comment 001-3: One commenter believed that proposed § 52.47 should require criteria for determining which non-safety-related SSCs are considered/categorized as important to safety.

NRC Response: The NRC does not agree that creating a definition of SSCs that are important to safety is within the scope of the Part 52 rulemaking. No changes have been made as a result of this comment.

Comment 001-4: One commenter suggested that in Subpart B – Standard Design Certifications, the term final safety analysis report (FSAR) should be replaced with the term standard safety analysis report (SSAR). The term FSAR is used in Subpart C – Combined Licenses to refer to a different submittal.

NRC Response: The NRC disagrees with this comment. In the past, design certification applicants have submitted SSARs, which were effectively the FSAR for the purpose of meeting the information requirements of the former § 52.47. The FSAR in Subpart C is not a different submittal and the FSAR for design certification will become part of the FSAR for a combined license. Therefore, future design certification applicants should submit an FSAR, as required by § 52.47(a).

Comment 001-5: One commenter notes that proposed § 52.47(a)(26) states that an application must include “an evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application.” The

commenter suggests that “(formally approved and issued)” should be added after “revision in effect” to minimize the current confusion about which SRP versions apply.

NRC Response: The NRC does not agree that the phrase “revision in effect” needs to be clarified.

Comment 001-6: One commenter believed that the articles of consideration for Part 52 or § 52.47 should state “(a) Conformance with draft SRP criteria is strictly voluntary, as long as the regulations are complied with.” This is because the issue of which SRP version applies causes much confusion.

NRC Response: The NRC does not agree with this comment. The evaluations of the plant design against the SRP criteria will facilitate future design reviews.

Comment 001-7: One commenter believed that the articles of consideration for Part 52 or § 52.47 should state “(b) The addressing of SRP criteria requiring site-specific and/or as-build equipment information should be the responsibility of the Combine License holder, and thus, should be deferred until after the start of construction.” This is because some information requested by an SRP cannot be provided until a site is finalized or a component is manufactured.

NRC Response: The NRC does not agree with this comment. The SRP is a guide for the NRC staff’s review of many different types of applications, including license amendments. The applicability of the SRP criteria is determined based upon the type of review being performed.

Comment 001-8: One commenter believed that the articles of consideration for Part 52 or § 52.47 should not apply to SSCs that meet the criteria in paragraph (c) of the comment.

NRC Response: The NRC does not agree with this comment. The applicability of various sections of the SRP are determined on an application-specific basis.

Comments 001-9, 001-10, and 001-11: One commenter suggested that proposed Part 52 should specify (a) the criteria for determining inspections, tests, analyses, and acceptance criteria (ITAAC), (b) that ITAAC are not required for confirmations that are covered by technical specifications surveillances, and (c) the categories of SSCs (e.g., safety-related SSCs or all SSCs important to safety as defined on a basic design basis) for which ITAAC should be provided. The levels of detail between ABWR ITAAC and the AP1000 ITAAC are not consistent and specific criteria for determining ITAAC are needed to ensure consistency. Technical specifications (TS) surveillances could perform the same function as the ITAAC, and having an ITAAC confirmation/validation a design feature or function already covered by TS surveillance(s) is redundant, and thus, unnecessary. Addressing SSCs that have no affect on safety (1) convolutes the understanding of a plant’s safety basis, (2) wastes industry and NRC resources for their generation and review, and (3) will eventually result in license amendment requests for non-safety changes that would otherwise be licensed under § 50.59, and thus, wastes additional NRC resources.

NRC Response: The NRC does not agree with these comments. First of all, the requirement for specifying ITAAC is already set forth in 10 CFR 52.97(b). Second, ITAAC is a verification

process for determining whether a plant should be authorized to operate. Whereas, technical specifications are operational requirements and they cannot perform the same function as an ITAAC verification. Third, ITAAC need to verify that the entire facility has been completed. Therefore, the scope of ITAAC covers the entire plant and the level-of-detail for ITAAC that verify structures and systems is proportional to the safety significance of those structures and systems. The level-of-detail for any particular ITAAC will vary for different designs. Finally, the criteria for license amendments, after the finding is made under § 52.103(g), are not dependent on ITAAC.

Comment 005-13: A commenter notes that on page. 12794 of the NOPR, the NRC describes its proposed process for allowing the Commission to make changes in design certification rules in 10 CFR Part 52. However, there is no discussion of the process by which the Commission would make a determination that, for example, a change to a DC rule would, in fact, constitute a reduction of regulatory burden. In addition, the provision that any such change would apply both to pending and planned COL applications and to plants that are currently operating ignores the fact that it is far easier and less expensive to make changes to “paper” designs than to an operating plant. Thus, “burden reduction” (which could be interpreted as including a cost-benefit evaluation) could not be assessed in the same fashion for operating and “potential” plants.

NRC Response: The NRC agrees with the commenter that the amount (if any) of burden reduction attributable to a proposed change in a design certification rule may differ for a hypothetical future license application referencing the design certification rule, as compared with an operating nuclear power plant referencing that design certification rule. Such issues will be addressed in the regulatory analysis (and possibly as part of the documentation for the Paperwork Reduction Act) that must be prepared for the proposed rulemaking, and will be considered by the Commission in determining whether to adopt the proposed change to the design certification rule by rulemaking. The Commission will be aided in these determinations by comments on the proposed rule that would amend the DCR. Licensees who believe that there would be little burden reduction (or, in fact, an increase in burden) attributable to a proposed change to a design certification rule will have the opportunity to submit such information to the Commission for its consideration as part of the notice and comment rulemaking process.

Comment 006-8: One commenter believed that it is inappropriate and unfair to apply provisions that are applicable to licensees to applicants for design certifications, given the fact that design certification applicants are not afforded the protections accorded to licensees under the law.

NRC Response: The Commission disagrees with the commenter that the proposed rule’s imposition on the design certification applicant of new regulatory obligations represents a fundamental shift in the nature of design certification which is “inappropriate...and unfair....” The choice of rulemaking versus licensing in design certification ultimately represents the Commission’s choice of the regulatory vehicle for providing its approval of a final reactor design. While it is true that the regulatory vehicle chosen will determine the manner in which regulatory obligations are imposed, the technical, regulatory and policy bases for the applicability of underlying NRC regulatory requirements exist regardless of the regulatory vehicle. For example, take the issue of reporting of defects in engineering on a reactor design. The public

health and safety need for prompt reporting to the NRC of such defects is the same regardless of whether the reactor design was submitted to the NRC for approval by license, or approval by rulemaking. That is why Section 206 of the Energy Reorganization Act of 1974, as amended, imposes reporting with regard to “any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended...(emphasis added).” The Commission rejects as untenable any argument that a rulemaking “imposing” the legal obligation of design certification applicants to report defects is inappropriate, or otherwise represents a “fundamental shift” in the nature of design certification.

The commenter did not identify the protections which are afforded to licensees under the AEA and APA but are not provided to design certification rulemaking applicants. Therefore, it is difficult for the Commission to address the commenter’s concerns. The one matter of which the Commission is aware of a difference between rulemaking versus licensing, is the protection of proprietary information. In a licensing proceeding proprietary information may be protected from disclosure in accordance with the applicable provisions of the Freedom of Information Act (FOIA). FOIA’s protections for proprietary information do not extend to information in a rule, or forming the bases for a rule; such information must ordinarily be disclosed in a rulemaking proceeding. However, this matter was thoroughly considered and addressed in the 1989 Part 52 rulemaking, and nothing in the 2006 proposed rule changes alters the Commission’s prior consideration of this issue with respect to design certification rulemaking. Moreover, although the commenter argues that “some of the proposed changes” are “not authorized by law,” the commenter does not identify the specific changes in the proposed rule falling into this category, which makes it impossible for the Commission to address the commenter’s concern on a specific basis. Nor does the commenter present any argument in support of this assertion or otherwise address the Commission’s discussion in the SOC for the proposed rule in which the Commission identified the statutory bases for the most significant obligations imposed on design certification applicants, namely, Parts 19 and 21.

For these reasons, the Commission has not made any changes to the final rule in response to the commenter’s suggestion.

Issues about SAMDAs

Comments 005-3 and 005-4: A commenter objected to the proposed requirement in § 52.47(b)(5) for design certification applicants to provide a separate environmental report that specifically addresses SAMDAs. Currently, a single analysis can be used to satisfy both the Part 51 NEPA-related requirement for a SAMDA assessment and the technical requirements of § 50.34(f)(1)(i). The commenter believed the proposed requirement (and other similar ones) should be deleted from the rule in favor of maintaining the process detailed in SECY-91-229. At a minimum, the environmental report should only be required if requested changes would cause a significant increase in risk.

NRC Response: The NRC does not agree with this comment. As stated above, SAMDA evaluations are required in order to achieve greater finality for the design features that are resolved in design certification rulemakings. Further, the NRC believes that the SAMDA environmental report should be separate from the final safety analysis report. Also, the risk assessment performed under § 50.34(f)(1)(i) is a subset of the design alternatives considered in the SAMDA evaluation. However, the NRC did revise the requirement for design certification

applicants [see § 52.47(b)(3)] to be consistent with the requirement in Part 51 (see § 51.55). In addition, the final rule is in conformance with the SRM on SECY-91-229, where the Commission approved the staff's recommendation to address SAMDAs for certified designs in a single rulemaking process that would consider both § 50.34(f) and the NEPA requirements in the design certification rulemaking.

Comments 005-6, 007-40, and 012-2: Several commenters believe that the requirements for a SAMDA evaluation in the proposed rule should be deleted. Instead, the NRC should initiate a rulemaking (rather than a plant-by-plant analysis) to generically determine that severe accidents in new nuclear plants are “remote and speculative” and that SAMDA evaluations are not required for new nuclear plants.

NRC Response: The NRC disagrees with this comment. The NRC has required SAMDA evaluations for previous applications for design certification in order to achieve greater finality for the design features that are resolved in design certification rulemakings. Further, the initiation of a rulemaking or policy statement for SAMDAs is outside the scope of the Part 52 update rulemaking. As for the perspective that SAMDA evaluations need not be performed for new nuclear plants because the severe accident risk for such designs is too remote and speculative. The NRC has already addressed this issue in other contexts. The NRC has considered petitions to eliminate the consideration of SAMDAs previously. The NRC position, both then and now is that it is not prepared to reach the conclusion that the risks of all severe accidents are so unlikely as to warrant their elimination from consideration in our NEPA reviews. As the NRC has stated in response to other requests to confine or eliminate such issues from consideration, if new information in the future provides a firm basis for concluding that severe accidents are remote and speculative, then the NRC may revisit the issue.

Comment 005-7: The requirement in 10 CFR 51.55 (p. 12882) for an applicant for an amendment to a DC to file a supplemental environmental report (ER) addressing changes in the outcome to a SAMDA assessment is far beyond the requirements that must be met for a licensee who wants to make changes to a plant licensed under 10 CFR Part 50. It would be preferable for this provision to be dropped altogether, but as a minimum, such an assessment should only be required if the requested changes would cause a significant increase in risk. Since the SAMDA assessment is a risk-based evaluation, it is reasonable to assume that design changes that do not increase plant risk would not change the result of a SAMDA assessment.

NRC Response: The Commission does not agree that the proposed provision in § 51.55 should be deleted or modified to limit the need to prepare an environmental assessment (EA) only if the requested changes would cause a significant increase in risk. An amendment to a design certification is a new rulemaking and, therefore, is a Federal activity or action under the National Environmental Policy Act. In implementing this provision of the rule, the Commission is limiting the environmental inquiry for a design certification rulemaking to an EA because the design certification rulemaking would not have a significant impact on the environment, and, furthermore, that the EA would be focused in scope to the consideration of SAMDAs. The Commission has determined that the potential significant impact on the environment from the certified design could only occur with the construction or operation of a nuclear power plant that references the design and such actions, such as the issuance of a combined license, would require the NRC to develop an environmental impact statement. Therefore, as stated in

§ 51.55, an applicant for a proposed amendment to a design certification must submit an environmental report that addresses SAMDAs. If the proposed amendment does not make changes to any portion of the design and the bases for the previous SAMDA analyses did not change, then the EA associated with the amendment to the design, which is a new design certification rule, can rely upon the earlier analyses (using tiering and incorporation-by-reference principles) and the staff will disclose that in its EA.

Comment 005-5: A commenter objected to the statement in the preamble that said SAMDAs are “alternative design features for preventing and mitigating severe accidents.” The commenter pointed out that the term itself does not include “prevention” of severe accidents, which is mentioned in § 52.47(a)(20).

NRC Response: The NRC disagrees with the commenter. Although the commenter is correct that the acronym, “SAMDA,” stands for “severe accident mitigation design alternatives,” the NRC has always understood the term to include design measures for the prevention of accidents. The NRC believes that consideration of severe accident prevention is prudent and consistent with NEPA, inasmuch as it is ultimately preferable to preclude the adverse environmental impacts from occurring through prevention of an accident, rather than tolerating a high probability of accident occurrence and instead attempting to mitigate the effects of the accident.

Concern about expanding scope of ITAAC

Comment 007-14: Several commenters noted that proposed § 52.47(b)(2) changes the scope of the ITAAC required for design certification from those needed to ensure conformance to the “design certification” to those needed to ensure that the plant conforms to the “design certification, the provisions of the Act, and the Commission’s rules and regulations.” The preamble explains that the proposed rule would conform to the requirement for acceptable inspections, tests, analyses, and acceptance criteria (ITAAC) with the Atomic Energy Act and the requirements in the current § 52.97(b). This clarification of the current language, which was a condensed version of the language in §§ 52.79(c) and 52.97(b), is intended to avoid any future misunderstandings. The commenters disagreed that this justifies the proposed change, or that the change is necessary to prevent “misunderstandings.” The language in Section 185.b of the Atomic Energy Act applies to COLs, not to design certifications. Given the smaller scope of a design certification, it is natural to apply different requirements to design certification ITAAC versus COL ITAAC. This proposed change could be misconstrued as expanding the scope of the ITAAC needed for design certification. Furthermore, it would be impossible for a design certification applicant to satisfy the literal language of this new provision, since the scope of the standard design does not encompass all of the design within the scope of the NRC’s rules and regulations.

NRC Response: The NRC does not agree with this comment. The clarification in § 52.47(b)(2) conforms with the AEA and provides the full and correct rule language for ITAAC, not the condensed version. It is important to remember that the design certification ITAAC will become part of the COL ITAAC. Also, this clarification will not be misconstrued with the requirement for the scope of design information needed for design certification, which is set forth in § 52.47(c). The requirements that are applicable to a certified design are defined by the scope of the design certification rule.

New Security Requirements for Design Certification and Design Approval Applicants

Comment 007-23: Several commenters noted that proposed 10 CFR§ 52.47(a)(24) and 52.137(a)(24) would specify that applications for a design certification or standard design approval must describe the design features needed to satisfy Part 73 regarding security. The commenters stated that the Supplementary Information for the proposed rule does not explain the need for or purpose of this proposed requirement as part of the current rulemaking. The commenters recommended that the Commission remove these proposed paragraphs from the current rulemaking and include appropriate provisions in a separate rulemaking specific to security design expectations.

The commenters stated that the proposed requirement is too broad and cannot be implemented as written. The commenters noted that many of the security design features required by Part 73 are outside the scope of the standard design and cannot be satisfied by a design certification applicant or an applicant for design approval. The commenters went on to state that a number of security design features will be site-specific and will be the responsibility of the COL applicant. The commenters recommended that therefore, at the very least, the language in the proposed rule on this point should be modified to indicate that applicants for design certification and design approval need only address those security design features that are within the scope of the standard design.

The commenters understand that there are five security rulemakings being developed. The commenters stated that any additional security requirements should be deferred to the security rulemakings and not included in a rulemaking on Part 52. The commenters stated that the security design expectations for new reactor licensing activities are the topic of a separate rulemaking activity which has been approved by the Commission in the Staff Requirements Memorandum on SECY 05-120 (Sept. 9, 2005). The commenters recommended that Part 52 should reference Part 73 and the other NRC requirements relating to security.

NRC Response: The NRC agrees with the comments. The paragraphs mentioned are now reserved.

Comment 007-24: Several commenters noted that proposed § 52.54(b) would require the design certification rule to specify “design characteristics.” Section 52.47 already requires that characteristics of the standard design be identified in the design certification application. In particular, the design characteristics are identified in the Design Control Document, which is incorporated by reference in the design certification rule. The commenters felt that it is unclear what more, if anything, is contemplated by the proposed rule, and anything more would be superfluous and confusing.

NRC Response: The NRC disagrees with this comment. The NRC wants to specifically identify site parameters and design characteristics in order to facilitate future comparisons with site characteristics and design parameters specified in an early site permit. The NRC staff will use its experience with the current early site permit reviews to determine what an appropriate list of design characteristics will be for future design certification reviews.

Submittal of FSAR or DCD

Comments 007-61 and 001-12: Several commenters pointed out that proposed § 52.47(a) would require that the DC application contain an FSAR. However, the NRC has required all design certification applicants to date to submit a Design Control Document (DCD), which largely duplicated the information submitted as part of the safety analysis report. Furthermore, it is the current practice of design certification applicants to submit a DCD and not a FSAR. To avoid burdensome and redundant submittals, incorporate an important design certification “lesson learned,” and conform to current NRC practice, proposed § 52.47(a) should refer to a DCD rather than an FSAR, or reflect that a DCD is effectively the FSAR for the purpose of the regulations.

NRC Response: The NRC disagrees with this comment. The requirement to submit an FSAR is not a redundant submittal. In the past, design certification applicants have submitted DCDs, which were effectively the FSAR for the purpose of meeting the information requirements of the former § 52.47. The reason that the DCD terminology was used in the past no longer exists and that terminology will not be needed in the future. Therefore, future design certification applicants should submit an FSAR, as required by § 52.47(a).

Comment 007-76: Several commenters supported proposed §§ 52.43, 52.45, and 52.47(b)(4).

NRC Response: No response necessary.

Some of the New Requirements Would Inappropriately Apply to Non-Light Water Reactors

Comment 020-1: The new requirements are written generically and would apply to all types of new reactors, including reactor types beyond light water reactors (LWRs). However, in some cases, the genesis of the requirements specifically arose and is applicable to LWRs only, and it would be inappropriate to apply the new requirements to non-LWRs. For example:

- The requirement for a design certification applicant to compare its design against the SRP should only be applicable to LWRs, since the SRP was developed and is specifically applicable only to LWRs. Applicants for other types of reactors, such as high temperature gas cooled reactors, should not be required to prepare a comparison against the SRP.
- The requirement for an evaluation of features to prevent and mitigate core melt accidents appears to reflect the intent of the NRC to codify the severe accident provisions in SECY-93-087. However, SECY-93-087 pertained only to light water reactors. Furthermore, core melt accidents are not credible in some Generation IV reactor designs, such as high temperature gas cooled reactors (HTGRs). In particular, HTGRs are not susceptible to the type of events specifically listed in the proposed rule, such as steam explosions, high-pressure core melt ejection, and hydrogen detonation. Therefore, there is no reason to require such designs to include an evaluation of features to prevent and mitigate core melt.
- Proposed Sections 52.47(a)(5), (6), (8), and (12) state, without limitation or qualification, that design applicants must meet the requirements in certain NRC regulations.

However, the regulations in question only pertain to LWRs. Thus, the proposed rule creates the potential for confusion, because the proposed rule might be erroneously construed as requiring all reactor types (not just LWRs) to satisfy the cited regulations. Therefore, we recommend that the proposed sections cited above be revised either to refer to LWRs (or, in some cases, pressurized water reactors) or to add the phrase "as technically relevant".

In short, several provisions in the proposed rule are inappropriate as applied to non-LWRs. At the very least, the NRC should modify those provisions to limit their applicability to LWRs.

NRC Response: The NRC agrees that there are various technical requirements, including those identified by the commenter (e.g., evaluation of core melt accidents, hydrogen detonation), which may not be applicable to non-LWR designs. However, it was not within the scope of the Part 52 rulemaking to evaluate the potential technical inapplicability of the Commission's regulations to non-LWR designs. To accomplish this task would have further lengthened the period of time necessary to complete this rulemaking. Such an expansion of the scope of this rulemaking seemed unwarranted, in light of other Commission regulatory activities with the goal of developing the appropriate technical infrastructure for advanced and non-LWR designs. These include the Technology Neutral Licensing Framework, and interactions with DOE on advanced burner reactor design. The Commission notes that most of the requirements in Part 50 are, for the most part, technology neutral, and have been applied in past AEC/NRC licensing actions for non-LWR designs, such as Peach Bottom, Fort St. Vrain, and the Clinch River Breeder Reactor. At least one potential combined license applicant (Exelon) has concluded that most of the technical requirements in Part 50 would be applicable to non-LWR designs that they were considering for a new nuclear power plant. Each of the current standard design certification applicants identified several technical requirements which they believed should not be applied to their design. The Commission provided dispensation from compliance with these requirements by including appropriate exemptions in each of final design certification rules. The same process may be used by future applicants for design certifications, including applicants for certification of non-LWR designs. Accordingly, the Commission has not adopted the commenter's proposal, and no change to the rule was made as a result of this comment.

The Commission also agrees with the commenter that the current SRP is written based upon LWR designs. However, the Commission disagrees with the commenter that applicants for other types of reactors, including the PBMR, should not be required to evaluate their designs against the SRP. First, there are a large number of areas within the SRP that are "technology-neutral" in the sense that the Staff review guidance applies regardless of the technology of the reactor under review. Second, the SRP is not a requirement, and indeed, the regulation simply requires the applicant to identify where the design has diverged from the guidance in the SRP. The purpose of this requirement is one of resources and planning: it allows the NRC staff to estimate areas which may require special resources, and a greater period of time, to perform an adequate safety review. The commenter did not set forth more specific reasons why the underlying goals of the requirement for evaluation against the SRP would not be served in the case on non-LWR designs.

5.3.4 Subpart C - Combined License

Incorporation of ESP ITAAC

Comment 003-13:⁴ Commenters noted that § 52.99(d) incorrectly referred to the ESP ITAAC. Commenters argued that when the COL is issued, it incorporates the ESP ITAAC, meaning the ESP would no longer be effective with respect to that COL.

NRC Response: The NRC agrees that the proposed language in § 52.99(d) that referred to requesting variances to ESP ITAAC after the COL is issued is inconsistent with rule language in other sections of Part 52 [e.g., § 52.39(d)]. Therefore, the NRC has adopted the commenters suggestion to delete references to ESP ITAAC and ESP variances from § 52.99(d).

ITAAC Completion

Comment 007-42: Several commenters noted that for ITAAC completed within the last 180 days before fuel load, proposed Section 52.99(c) would require the COL holder to notify the NRC within 10 days of successful ITAAC completion. The commenters stated that this requirement is unnecessary and recommended that it should be deleted. The commenters noted that the licensee will be highly motivated to notify the NRC of successful ITAAC completion as quickly as possible so as to trigger the NRC's ITAAC verification process.

The commenters stated that processes for expediting ITAAC verification during the critical last 6 months before fuel load should be considered in an integrated and comprehensive way outside the rulemaking context. The commenters asserted that rule changes are not necessary. Rather, the commenters recommended such processes be discussed as part of the ongoing joint industry-NRC ITAAC Demonstration Project. The commenters intend to document common understandings about ITAAC implementation and verification, including special processes for managing the ITAAC verification in the last 6 months before fuel load, in NEI 06-01, "COL Implementation Guideline."

NRC Response: The NRC agrees, in part, with this comment. The NRC has decided that it does not need to specify a time period for the licensee to notify the NRC of the successful completion of ITAAC and the proposed requirement for a 10-day notification was deleted from § 52.99(c). However, the licensee's notifications will affect the timing of the NRC's conclusion's regarding whether ITAAC have been successfully completed. In addition, the NRC has added a new provision to § 52.99(c) dealing with the last 6 months before initial fuel loading. This new provision is discussed in Section V.C.8.b of the "Supplementary Information."

Comment 013-5: A commenter recommended that the NRC should provide clear guidance for verifying completion of ITAAC. The commenter noted that such guidance is necessary given the central importance of ITAAC to the Part 52 licensing process, during which the Commission may find, in deciding whether to issue a COL, that ITAAC criteria have been satisfied and may be excluded from the COL (proposed 10 CFR § 52.97(a)(2)). The commenter stated that the

⁴Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI's comments submitted on May 25, 2006. Therefore, all of these commenters are included in each of NEI's May 25, 2006 comments (comment number 003). For simplicity, these comment numbers are not repeated in this document for each comment.

recommended guidance would include clarification on expediting ITAAC verification and on special processes for managing ITAAC verification in the last 6 months prior to fuel load, pursuant to the ongoing industry-NRC joint discussions and as described in NEI 06-01, "COL Implementation Guideline."

NRC Response: The NRC agrees with this comment and intends to issue regulatory guidance on the process for completing ITAAC. The NRC notes that the information that is necessary to demonstrate that ITAAC have been successfully completed will be the same before and after issuance of the combined license.

Comment 007-67: Several commenters pointed out that proposed § 52.47(b)(4) provides that ITAAC related to verifying compliance with interface requirements may be performed "either in the plant or elsewhere." The commenters recommended also adding the language "either in the plant or elsewhere" to §§ 52.47(b)(2) and 52.80(b) of the final rule.

NRC Response: The NRC disagrees with this comment. Inclusion of the statement "either in the plant or elsewhere" in the rule language is not necessary and the phrase has been deleted from the final rule language. The NRC recognizes that some testing, i.e., type tests, will be performed outside of the plant and these tests will be identified in the ITA column of the ITAAC tables. Also, tests and inspections may be performed at the locations where the components are fabricated. The tests and inspections that need to be performed under as-built conditions should be identified in the ITAAC or supporting documentation.

Section 52.103 Hearings

Comments 003-14, 003-4, 003-15, and 003-16: Several commenters stated that the hearing procedures described in § 52.103 and Part 2 need to be modified. Commenters believed the NRC should specify that § 52.103 hearings (the "ITAAC hearing") would be legislative hearings under Subpart O of Part 2. Commenters preferred the use of Subpart O over Subpart N because: (1) Subpart N contemplates a hearing that is not expected to require more than two days to complete, and (2) Subpart N requires all parties at the proceeding to agree the hearing should be conducted under that Subpart. Commenters noted that the "non-adversarial" nature of Subpart O-type legislative hearings (See 69 FR 2182, 2192, January 14, 2004) (NRC final rule amending rules of practice in 10 CFR Part 2) made them well-suited to the development of "legislative facts," viz., general facts which help a decisionmaker decide questions of policy and discretion."

To support the use of this type of hearing, commenters argued a legislative hearing would be consistent with § 189.a.(1)(B)(iv) of the Atomic Energy Act of 1954, as amended (AEA), and would meet the NRC's obligation under 10 CFR 52.103 to provide an opportunity for a hearing on whether the inspections, tests, analyses, and acceptance criteria for the new nuclear facility had been satisfied. Commenters stated that the NRC was required to hold formal, on-the-record hearings under the Administrative Procedure Act only if the agency's governing statute, the AEA, mandated such formal hearings. Commenters claimed the AEA did not mandate formal, on-the-record hearings for COL applications under 10 CFR Part 52 § 185.b of the Act. Commenters stated the NRC will conduct initial licensing hearings for COL applications under 10 CFR Part 2, Subpart L (informal hearing procedures). Commenters stated the AEA does not require formal, on-the-record hearings for the 10 CFR 52.103(d) ITAAC hearing. Commenters

referenced AEA § 189.a.(1)(B)(iv) and argued the language of NRC regulations in § 52.103(d) was essentially identical to this statutory provision. Commenters noted the AEA narrowly focuses the § 52.103 hearing opportunity on “whether the facility as constructed complies, or on completion will comply, with the acceptance criteria of the license” (See AEA § 189.a.(1)(B)(I)). Commenters contended that legislative hearings would be appropriate for resolving disputes regarding ITAAC satisfaction given the objective nature of most of the ITAAC. Commenters recommended changes be implemented by either: (1) issuing an order in each licensing proceeding, or (2) codifying the change by amending the language of existing 10 CFR Part 2, Subpart O (including §§ 2.1500 and 2.1502) to specify that Subpart O legislative hearings would be used to meet the NRC’s obligation under 10 CFR 52.103(d) to hold a hearing leading to the issuance of findings required under 10 CFR 52.103(g).

Commenters proposed that the NRC modify its hearing process to provide that, in deciding whether to grant a request for a hearing pursuant to § 52.103, the presiding officer first determine whether a contention was exempt from adjudication under § 554(a)(3) of the Administrative Procedure Act (APA) (5 U.S.C. § 554(a)(3)) and § 185b. of the AEA. Commenters noted that: 10 CFR 52.103(b) provides that a request for hearing under § 52.103(a) must show, prima facie, that (1) one or more of the acceptance criteria in the COL have not been or will not be met, and (2) the specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety. Commenters explained that APA § 554(a)(3) exempts from APA formal adjudication requirements those matters in which decisions “rest solely on inspections, tests and elections.” Commenters argued that the scope of the § 554(a)(3) exemption has generally been construed to include “technical facts ... as to which administrative hearings have long been thought unnecessary” and situations where an agency relies on the “judgment” of a tester or inspector. [Door v. Donaldson, 195 F.2d 764 (D.C. Cir. 1952); see also Attorney General’s Committee on Administrative Procedure, Final Report to President and the Congress, at 37 (1941) (noting that “resort to formal procedures... is not desired or utilized ... because it gives no added protection”); S.Rep. No. 752, 79th Cong., 1st Sess. 16 (1945) (exempting inspections, tests, and elections “because those methods of determination do not lend themselves to the hearing process”).]

Commenters believed that the APA § 554(a)(3) exemption relieves the NRC of the obligation to conduct any hearing under § 52.103 when the question of whether a new facility complies with an ITAAC can be decided solely on the basis of inspections or test results. To validate this belief, commenters noted that in *Union of Concerned Scientists v. U.S. Nuclear Regulatory Commission*, the Court acknowledged that Congress did not intend to require a hearing where it would serve no purpose, though exemption from AEA was not an exemption from APA § 554 procedures. (735 F.2d 1437, 1449 1450, D.C. Cir. 1984).

Commenters suggested that to remain consistent with APA § 554(a)(3), the NRC could exclude those specific “inspections, tests, and analyses” referenced in AEA § 185b. that rely solely on detailed, objective, or self-implementing acceptance criteria that do not lend themselves to the hearing process. Commenters stated that the NRC has in fact taken such action in the past (see November 20, 2003, NRC letter to NEI on combined license topic COL-5 concerning the 10 CFR 52.103 hearing process, p. 4). Commenters claimed that by limiting the scope of § 52.103 hearings to those ITAAC that actually had a component amenable to the informal hearing process, the NRC could more efficiently focus the pre-operational hearing process, save time by focusing on those ITAAC that involve issues that fall outside the APA exception,

and promote stability in the licensing process. Commenters claimed the position they were advocating was consistent with principles acknowledged by the NRC when it promulgated the original 10 CFR Part 52 (54 FR 15372, 15380, April 18, 1989). Commenters requested that the NRC not prejudge whether acceptance criteria raised under § 52.103 would be “self limiting.” Commenters suggested that to assure correct identification of which ITAAC were susceptible to resolution based solely on the results of tests and inspections, and thus should not be adjudicated, the NRC could: (1) delegate this determination to the NRC staff with technical expertise, (2) make determinations on a case-by-case basis, or (3) allow the presiding officer in the § 52.103 hearing to decide.

NRC Response: The Commission disagrees with the commenter’s suggestion that the final rule should require the use of subpart O hearing procedures. It is premature, given the lack of any experience in the use of subpart O procedures, as well as the lack of any experience in ITAAC hearings under § 52.103(g), to require by rule the use of these procedures. The Commission is not adverse to considering the use of subpart O procedures in a § 52.103 hearing (a matter for which the Commission declines to express an opinion at this time), and if so, whether Commission direction should be provided by generic guidance, or through case-specific Commission action. However, the Commission does not believe it to be prudent to require the use of those procedures in a rulemaking. Accordingly, the Commission declines to adopt the commenter’s proposal, and no change to any part of the final rule has been made as the result of the comment.

The Commission agrees with the commenter that Section 554(a)(3) exception of the Administrative Procedures Act may be used to in appropriate circumstances to avoid a § 52.103 hearing on whether a specific ITAAC (or portion of an ITAAC) has been satisfied. However, as the commenter notes, there are many alternative approaches for the NRC to make the determination of which ITAAC fall within the ambit of the APA exception. See May 25, 2006 NEI letter, p. 14. There has never been a § 52.103 hearing, so there is no applicable experience that the Commission could draw upon when formulating a generic rulemaking requirement. None of these alternatives (and other alternatives identified within the NRC) were discussed in the SOCs for either the 2003 or 2006 proposed rules. Adopting by rule a particular approach for invoking the Section 554(a)(3) exclusion, under these circumstances, is likely to result in adverse public assessments of the Commission’s actions. Finally, the need for resolution of this issue as part of this rulemaking is not clear, given that such hearings are unlikely to occur until well into the next decade. Accordingly, the Commission concludes that adoption of detailed rulemaking requirements governing the use of the Section 554(a)(3) exception in this final rulemaking would not be prudent.

New Requirements Applicable to COL Amendments

Comment 007-26: Several commenters noted that proposed 10 CFR 52.98(a) states that “after issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of § 52.103 or § 50.109 of this chapter, as applicable.” Overall, the commenters support the provisions in proposed § 52.98. The commenters stated that in particular, the intent of proposed § 52.98(a) appears to be appropriate, since it would restrict the Commission’s

unilateral ability to impose changes without the appropriate justification under the backfit rule in § 50.109. The commenters continued, and asserted that it appears that § 52.98(a) as written would not allow the Commission to make a change at the request of the COL holder unless the change meets the backfit rule.

The commenters noted that the December 27, 2005, NRC staff response to the Commission's Staff Requirements Memorandum on the proposed revisions to Part 52 states that it is not the intent of the NRC to impose the backfit criteria on license amendment requests by a COL holder. The commenters stated that in contrast the actual language used in the proposed rule does not reflect that intent. The commenters recommended that the proposed provision should be modified to clarify that the NRC may issue license amendments at the request of the licensee without the need for the licensee to demonstrate that the backfit criteria are satisfied.

NRC Response: The Commission does not agree with the commenter's position that a change to § 52.98(a) is needed to clarify that the Commission may issue an amendment requested by a combined license holder with respect to matters which are not derived from a referenced standard design certification or manufacturing license, without meeting the backfit criteria in §52.103 or § 50.109. Paragraph (a) is meant only to address limitations on the Commission's imposition of changes to the license (similar to § 52.39(a) for ESPs). Other provisions address the licensee's ability to request changes to the COL, most notably, § 50.90 and §§ 52.98(b), (c), and (d). However, even if one were to interpret this language as requiring compliance with the backfitting provisions in 50.109, the Commission has long interpreted the term, "backfitting," under § 50.109 as excluding voluntarily-initiated licensee requests for, inter alia, license amendments. Accordingly, there is no need to clarify the language of this section in the manner proposed by the commenter.

New Requirements for Construction Completion Dates

Comment 007-33: Several commenters noted that proposed §§ 50.23, 52.77 and 52.79(a)(39) would require a COL application to state the earliest and latest dates for completion of construction. The commenters stated that the requirement to specify a construction completion date should only be applicable to construction permits, and not to combined licenses. The commenters recommend that NRC delete the requirement to specify the earliest and latest dates for completion of construction for a combined license.

The commenters noted that there currently is no requirement for a COL to specify the completion dates for construction. The commenters also noted that when the NRC amended its regulations in 1992 to reflect provisions of the Energy Policy Act of 1992, it specifically removed the provision that would have required a COL applicant to state the earliest and latest dates for completion of construction. [57 FR 60975, December 23, 1992] The commenters noted that the basis for removing this requirement was that it was "no longer required under the legislation." [Id., 60976]

The commenters stated that, in particular, Section 185.a of the Atomic Energy Act requires that a construction permit state the earliest and latest dates for completion of construction. The commenters noted that in contrast, Section 185.b, which addresses a combined license, does not require a COL to specify a construction completion date, nor does it specifically impose the requirements of Section 185.a.

The commenters stated that the Supplementary Information for the proposed rule does not explain why the NRC has changed its view of the requirements in Section 185, other than simply to suggest that the NRC now believes the construction permit provisions in Section 185.a are applicable to a combined license. The commenters asserted that, absent any valid basis for changing its view of the Energy Policy Act of 1992, the NRC should not impose this unnecessary and inappropriate requirement.

The commenters stated that the requirement to specify a construction completion date represents an undue administrative burden with no useful purpose, and the requirement should not be extended beyond the explicit language in Section 185.a (i.e., it should not be extended beyond construction permits). The commenters noted that the experience for Part 50 plants demonstrates that the costs of such a requirement can be substantial. The commenters noted as examples that these costs may include the costs of preparation of requests to extend the completion dates when construction was delayed, the costs of NRC review of such request, and in some cases the cost of expensive hearings on the extension requests. Furthermore, the commenters noted that the NRC routinely granted timely extension requests, without addressing any safety issues and therefore there was no useful purpose served by extension requests or the requirement to specify a construction completion date.

The commenters also noted that the industry does not object to informing the NRC of its expected construction schedules. The commenters understand that the NRC needs such information to plan its construction-related inspections. The commenters stated their expectation that COL applicants will provide construction schedule information to NRC, which is documented in NUREG-1789, Part 52 Construction Inspection Program Framework Document, and most recently in an April 4, 2006, NEI letter to NRC identifying “lessons learned” from the joint industry-NRC ITAAC Demonstration Project.”

NRC Response: The Commission agrees with the commenters that the combined license application need not specify the earliest and latest date for completion of construction, in light of the amendment to Section 185 of the AEA that was made by the Energy Policy Act of 1992. By adding a new Section 185.b., the Commission believes that Congress intended that Section 185.b supersede Section 185.a, so that the Section 185.a requirements for “stand-alone” construction permits, such as the need to specify the earliest and latest date for completion of construction, do not apply to the construction permit portion of a combined license under Section 185.b. Furthermore, by amending only Sections 185 and 189 to specifically address combined licenses, the Commission believes that Congress did not intend to repeal by implication AEA requirements for operating licenses with respect to the operating license portion of a combined license. This is supported by the Report of the Senate Committee on Energy and Natural Resources:

This Section [9101] redesignates Section 185 of the existing Atomic Energy Act as subsection a. and adds a new subsection b. Subsection a. will continue to govern the issuance of construction permits and operating licenses following completion of plants initially granted a construction permit under the old “two-step” licensing process. The new subsection b. will govern the issuance of a combined construction and operating license and the commencement of operation under a combined license.

S. Rep. No. 102-72, 102nd Cong, 1st Sess., p. 292 (1991). Accordingly, the final rule removes the requirements from §§ 50.33(h), 52.77, and 52.79(a)(39) that the combined license application specify the earliest and latest date for completion of construction.

Provisions Recognizing that ITAAC May Be Performed Either in the Plant or Elsewhere Should be Expanded

Comment 007-67: Several commenters pointed out that proposed § 52.47(b)(4) provides that ITAAC related to verifying compliance with interface requirements may be performed “either in the plant or elsewhere.” The commenters recommended also adding the language “either in the plant or elsewhere” to §§ 52.47(b)(2) and 52.80(b) of the final rule.

NRC Response: The NRC disagrees with this comment. Inclusion of the statement “either in the plant or elsewhere” in the rule language is not necessary and the phrase has been deleted from the final rule language. The NRC recognizes that some testing, i.e. type tests, will be performed outside of the plant and these tests will be identified in the ITA column of the ITAAC tables. Also, tests and inspections may be performed at the locations where the components are fabricated. The tests and inspections that need to be performed under as-built conditions should be identified in the ITAAC or supporting documentation.

Contrary to the Proposed Rule, Not All ESP Conditions and Certification Requirements Can Be Completed Prior to Issuance of the COL

Comment 007-52: Several commenters noted that proposed 10 CFR 52.79(b)(3) and § 52.79(d)(3) would require that the FSAR demonstrate that all ESP conditions and certification requirements will be satisfied by the date of issuance of the COL. The commenters stated that it may not be possible to complete all ESP conditions prior to issuance of the COL. The commenters noted as an example that there may be ESP conditions applicable to improvement of subsurface conditions that must be implemented under an approved quality assurance program (i.e., after the COL is issued). The commenters also noted that similarly, it may not be possible to complete all design certification requirements prior to issuance of the COL. The commenters noted as a final example that some of the COL action items specified in the DCD cannot be implemented until construction or initial testing. The commenters recommended that the proposed rule should therefore be modified to account for these possibilities. The commenters recommended that §§ 52.79(b)(3) and (d)(3) be modified to add this phrase to the end, “or the final safety analysis report must include provisions to implement those conditions that cannot be implemented until after the license is issued.”

NRC Response: The NRC agrees in part with the commenters. The NRC agrees that it may not be possible to complete all ESP terms and conditions prior to issuance of the COL and that a similar situation exists for design certifications. Also, although not mentioned by the commenter, the same is true for manufacturing licenses. Therefore, the NRC is making changes in the final rule to several sections. The NRC is revising §§ 52.79(b)(3) and 52.79(d)(3), which were mentioned by the commenters. The NRC is also revising §§ 52.24 (b) and 52.79(e)(3), which contain similar language but were not mentioned by the commenters. However, the NRC is not adopting the commenters’ suggested rule language which would have allowed applicants to address ESP terms and conditions in the COL FSAR. Instead, the NRC is adding language that would require that any terms or conditions of the early site permit that

could not be met by the time of issuance of the combined license be set forth as terms or conditions of the combined license. The NRC believes that any issue that was important enough to be included as condition of the ESP warrants being included as a condition of the COL if it cannot be met prior to issuance of the COL.

Clarification of the Section 50.59 Change Process for COLs

Comment 007-64: Several commenters noted that proposed 10 CFR§ 50.59(b) and 52.98 would make the change process in § 50.59 applicable to holders of COLs. The commenters also noted that under the existing provisions in Section 50.59(c), certain types of changes require a license amendment. The commenters agree that § 50.59 should be applicable to COL holders as soon as the COL is issued. However, the commenters stated that during the period of construction, they believe that a clarification of the 50.59 process is warranted.

The commenters noted that language in existing § 50.59 guidance in NEI 96-07, Guidelines for 10 CFR 50.59 Implementation, which has been accepted by the NRC in Regulatory Guide 1.187, Section 4.5, discusses when an activity is considered “implemented.” The commenters stated that many times during construction, minor changes are needed or minor nonconformances arise that are acceptable as-is from a safety perspective. The commenters suggested that for those changes needing NRC approval under § 50.59, it should be acceptable to make the change at the risk of the licensee, document and control the change as an issue needing further approval, and then confirm the acceptability of the change after the fact to allow construction activities to proceed pending NRC approval of a license amendment. The commenters recommended that this should be permitted for any changes to structures, systems, or components that have not yet been placed in service. The commenters noted that such a process would be consistent with the existing guidance in NEI 96-07 that is referenced above.

NRC Response: The NRC generally agrees that it would be appropriate to apply the guidance outlined in NEI 96-07 and accepted in NRC Regulatory Guide 1.187 regarding when an activity is “implemented” to COLs during construction. The NRC does not believe, however, that any change to the proposed rule language or statements of consideration is necessary.

Support for Conforming Changes and Other Beneficial Proposals

Comment 007-69: Several commenters suggested one additional change to Part 52 that it and its constituents consider necessary to ensure that the regulations are consistent and conform to the Energy Policy Act of 2005 and previous rulemakings.

The commenters recommended that the NRC amend existing § 52.83 to change the reference from § 52.99 to § 52.103(g) as to when the requirements applicable to operating licenses apply. The commenters stated that this would be a correction, and is not intended to be a substantive change. The commenters recommended that this same change should be made to clarify that a Part 52 COL 40-year license term begins at the time the § 52.103(g) finding is made (rather than the § 52.99 finding). The commenters noted that this would also be consistent with the duration of a combined license in the Energy Policy Act of 2005, Section 621. The commenters believe that the proposed rule adequately addresses this issue.

The commenters also recommended that the NRC amend existing § 52.85 to correct the reference to Part 2, Subpart G, hearing requirements. The commenters noted that this paragraph should have been changed in the 2004 rulemaking that amended 10 CFR Part 2. The commenters noted that the paragraph could simply reference Part 2 as the governing regulation for hearing procedures. The commenters believe that the proposed rule adequately addresses this issue.

NRC Response: No response necessary.

Beneficial Changes Proposed for Part 52

Comment 007-77: Several commenters stated that the industry considers the changes in the NOPR in § 52.79(b), (c), (d), and (e), regarding contents of FSARs; in §§ 52.80(b) and 52.97(a)(2), regarding provisions for completion of ITAAC at the COL stage; in § 52.85, regarding administrative review of applications and hearings; in § 52.98, regarding finality of combined license and information requests; in § 52.103, regarding ITAAC hearing and finding process; and in § 52.104, regarding 40-year duration of combined license, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

Comment 011-2: A commenter noted that in § 52.79(b) on page 12900 of the *Federal Register* notice, the paragraph starts “If the application for a safety analysis report...” The commenter argued that “[Applicants] don’t apply for an SAR.” The commenter suggested that it should read either “If the application...” or “If the applicant’s safety analysis report...”

NRC Response: This was an inadvertent error in terminology in § 52.79(b). In the final rule, the NRC has corrected the paragraph to read, "If the combined license application references an early site permit, then the following requirements apply."

Comment 011-5: A commenter noted that in 10 CFR 52.79(b)(3) there is a requirement for COL applicants referencing an ESP to demonstrate that all ESP terms and conditions associated with the FSAR are met. The commenters stated that there doesn’t appear to be an equivalent requirement for environmental terms and conditions. The commenter asked if there should be such a requirement listed in the final rule. [See discussion on § 52.79(b)(3) in Section C.6.f of the NOPR Supplementary Information, pages 12,793 and 12,901.]

NRC Response: The NRC agrees that there should be requirements that a COL applicant referencing an ESP demonstrate that all ESP terms and conditions are met, including environmental terms and conditions. The NRC has added a requirement for COL applicants to address ESP environmental conditions in § 51.50(c)(1) in the final rule.

Allow COL Applicants to Describe Existing Part 50 Operational Programs in a COL Application

Comment 013-6: A commenter recommended that NRC should eliminate ambiguities between Part 50 substantive safety requirements and Part 52 licensing processes. The commenter suggested that a COL applicant should be able to credit existing operational programs that support approval of the COL without ITAAC for such operational programs. The commenter

supports the NRC proposed language to allow COL applicants to describe existing (Part 50) operational programs in a COL application (proposed 10 CFR § 52.79), thereby eliminating the need for duplicative information submittals and NRC reviews.

NRC Response: No response necessary.

Scope of COL Hearings

Comment 013-8: A commenter recommended that the NRC should clearly specify what items are properly included in the scope of COL hearings by placing proper limits on issues resolved in ESP proceedings to eliminate redundant litigation of ESP siting issues in COL or other future licensing proceedings involving a referenced ESP. [See also excerpt 007-8 in Section 5.3.2 of Comment Summaries.]

NRC Response: The NRC agrees that it is important to clarify what items are properly included in the scope of COL hearings in the case where the COL applicant is referencing an ESP. The NRC has made changes to §§ 52.39 and 51.105 in the final rule to address this issue.

Procedures and Schedules for Completion of Pre-operational Hearings

Comment 013-9: A commenter recommended that the NRC carefully control the procedures and schedule for completion of any pre-operational hearing contemplated by 10 CFR § 52.103. The commenter notes that the current framework in Part 52 establishes a compressed schedule (180 days to render a decision from the notice of intended operation) and creates the risk of delaying fuel load and plant startup.

NRC Response: The NRC agrees that NRC must carefully control the hearing procedures and schedule for completion of any hearings associated with the finding under § 52.103(g), as well as ensuring timely determinations that may be needed under § 52.103(c). Several provisions in §§ 52.99 and 52.103 of the final rule were added to support: (i) the conduct of fair, efficacious and timely hearings associated with the finding under § 52.103(g), as well as (ii) timely determinations under § 52.103(c).

NRC Licensing Board Decision Timeframes

Comments 003-11: Several commenters recommended that NRC Licensing Boards should be directed to issue a decision in the 10 CFR § 52.103 hearing within 30 days of the close of that proceeding. The commenters suggested that Licensing Boards would be allowed to deviate from those time limits only with the prior approval of the Commission.

NRC Response: The NRC disagrees with the commenters. The NRC believes, in light of the lack of any NRC experience in the conduct of § 52.103(g) hearings, as well as the lengthy period of time before there will be an opportunity to request a § 52.103(g) hearing, that it is premature to establish in this rulemaking a binding requirement by rulemaking that the presiding officer issue a decision in any § 52.103(g) hearing within 30 days of the closing of the record in the proceeding.

COL Referencing Use of a Manufactured Reactor

Comment 005-23: A commenter noted that on page 12797 of the NOPR, there is a discussion on the proposed requirements in § 52.79(e) for a COL application referencing a “manufactured reactor.” The commenter stated that it appears the reference here should be to a manufacturing license (ML).” The commenter continued, stating that the discussion of siting information in that section is confusing. The commenter recommended that the section should say that the COL application must provide information sufficient to demonstrate that the site characteristics for the site where the manufactured reactor is to be installed are bounded by the site parameters assumed in the license, rather than “the site parameters for the manufactured reactor are bounded by the site” where the reactor will be installed.

NRC Response: The Commission disagrees with the commenter that § 52.79 should refer to a combined license application referencing a manufacturing license, as opposed to the manufactured reactor. A nuclear power plant to be constructed and operated under a combined license would utilize a nuclear reactor - i.e., a physical facility,” rather than an intangible manufacturing license. Moreover, the combined license would not authorize any “manufacturing” under a referenced manufacturing license; all manufacturing of the reactor would be completed before the manufactured reactor was shipped off-site. Accordingly, it is correct to require the combined license application to reference the use of the manufactured reactor, rather than manufacturing license under which the reactor had been manufactured.

The Commission agrees with the commenter that the SOC discussion (71 FR at 12797, second column) is confusing with respect to the siting information that must be provided in a combined license application referencing the use of a manufactured reactor. The SOC and language of proposed § 52.79(e)(1) should have referred to “site characteristics,” rather than, “site.” Moreover, the Commission also notes that § 52.79(e)(1) does not follow the analogous language in 52.79(d)(1). The Commission has addressed this problem in the final Part 52 rule by conforming the language of both paragraphs.

5.3.5 Subpart E - Design Approvals

New Requirement for Design Approvals to Address Emergency Facilities

Comment 007-34: Several commenters noted that proposed 10 CFR 52.137(a)(22) would require that an applicant for a standard design approval include design information on coping with emergencies. The commenters stated that the proposed rule makes no reference to this change, and the purpose and intent of this provision is unclear. The commenters recommend that the NRC delete proposed § 52.137(a)(22).

The commenters asserted that this requirement, taken literally, cannot be satisfied. The commenters stated that the standard design approval applicant will not be responsible for certain emergency planning design features, including the Emergency Operations Facility and other offsite emergency design features (such as sirens). The commenters noted that such design features will be the responsibility of the COL applicant.

The commenters also noted that the same provision is not included in the scope of proposed requirements for a design certification. The commenters stated that it is unclear why an

application for design approval should be subject to greater requirements than an applicant for design certification.

NRC Response: The NRC disagrees with this comment. The requirement to address design features that affect plans for coping with emergencies in the operation of the reactor facility is not a new requirement. This requirement has existed in the former Appendix O to Part 52 (see the last sentence of item #3) for decades and has been adequately addressed in previous final design approval applications. The proposed rule did not discuss this requirement because it was in the former rule. Furthermore, the commenters are misinterpreting this requirement. It does not apply to offsite emergency design features, i.e., sirens.

Elimination of the Option of Renewing a Standard Design Approval

Comment 007-47: Several commenters noted that proposed § 52.147 would prohibit renewal of standard design approvals. The commenters stated that the Supplementary Information for the proposed rule provides no explanation or basis for the prohibition on renewal of a standard design approval. The commenters asserted that a design approval should be subject to renewal, just as a design certification, ESP, and COL are subject to renewal. The commenters stated that there is no reason to prohibit renewals of design approvals.

NRC Response: The NRC does not agree with this comment. The original Appendix O to Part 52 did not contain a process for renewing design approvals and most of the design approvals issued under Appendix O were for a 5-year duration. In this rulemaking, the Commission has tripled the duration for a design approval and believes that renewals will not be necessary. Also, as stated before, the Commission favors the use of the design certification process, which includes a process for renewals.

Beneficial Changes Proposed for Part 52

Comment 007-78: Several commenters stated that the industry considers the changes in the NOPR in § 52.147, regarding the 15-year duration of a standard design approval, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.3.6 Subpart F - Manufacturing Licenses

Limitations on Manufacturing Licenses - number of reactors manufactured, term of license, initiation of manufacture in 3-year period before expiration

Comment 007-48: Several commenters noted that proposed § 52.167(b)(3) would limit the number of reactors that may be manufactured under a manufacturing license to that number of reactors whose start of manufacture could practically begin within a 10-year period. The commenters also noted that proposed § 52.173 would allow the manufacturing license to be valid for not less than 5, nor more than 15 years from the date of issuance, and would permit renewal. However, the commenters went on to note that proposed §§ 52.173 and 52.177(c) would impose the restriction that a manufacturer may not initiate manufacture of a reactor less

than 3 years before the expiration of the license, even though a timely application for renewal has been filed with the NRC.

The commenters stated that the Supplementary Information for the proposed rule provides no justification for establishing these requirements and limitations, other than stating that the 3-year period provides “a reasonable period for completing the manufacture of a nuclear power reactor, based in large part upon public statements by various reactor vendors that they have set goals for constructing complete nuclear power plants onsite within 3 years.” In the commenters’ view, there is no practical reason to impose such restrictions. The commenters stated that if a plant design that is the subject of a manufacturing license remains technically viable to purchasers, the NRC should not unduly restrict the market by removing the vendor’s capability to meet the needs of its customers. Further, the commenters stated that there appears to be no basis related to safety for restricting the use of the manufacturing license as long as the manufacturing is conducted in accordance with the terms of the license.

NRC Response: The Commission, upon further consideration, has decided to remove the requirement from proposed § 52.167(b)(3) with respect to the number of nuclear power reactors authorized to be manufactured. The Commission agrees that if a manufactured nuclear power reactor continues to be commercially viable throughout the term of the manufacturing license, there should be no reason why the Commission should restrict in the manufacturing license the number of reactors that can be manufactured under the license. Moreover, including such a limit may actually serve as a disincentive for the manufacturer to improve the efficiency and productivity of manufacturing, inasmuch as the license limits the number of reactors that may be manufactured. Accordingly, the Commission has removed the requirement in § 52.167(b)(3) that the manufacturing license specify the number of reactors authorized to be manufactured.

The Commission established the five (5) and fifteen (15) year minimum and maximum term of license to be generally consistent with the term of a standard design certification. The Commission believes that the term of a design certification is an appropriate starting point because both regulatory approaches involve NRC approval of the final design of a reactor and the period in which the approved design may be utilized.

The Commission disagrees with the commenter’s proposal that the three-year restriction on commencement of manufacture of a reactor in both §§ 52.173 and 52.177(c) should not be adopted in the final rule. As stated in the SOC, 71 FR at 12801, the Commission established the 3- year deadline for timely submission of an application for renewal of the manufacturing license, consistent with the Timely Renewal Doctrine of the APA. The Commission clarifies that the 3-year deadline for filing of a timely renewal application is intended to ensure that the NRC completes action on the renewal application before the term of the license expires so that recourse to the Timely Renewal Doctrine is unnecessary. This is consistent with the Commission’s rationale in 1989 when it established the period for timely filing of a renewed operating license for nuclear power plants under Part 54 of this chapter. The Commission continues to believe that public confidence in the regulatory process is maintained by establishing a renewal application deadline in this fashion. Accordingly, the Commission declines to adopt the commenter’s suggested change to § 52.173, and no change to the final rule has been made in this regard as the result of the comment.

The Commission also disagrees with the commenter’s proposal that § 52.173 should be modified to allow the manufacture of new reactors to commence after expiration of the

manufacturing license, so long as a timely application for renewal has been filed. The Commission does not believe that commencement of manufacture of a new reactor (as opposed to completion of a reactor whose manufacture has already started at the time of filing for renewal) is an activity of a “continuing nature” for which the timely renewal provision in the APA applies. 54 FR 64962-63⁵. Moreover, analogous to the “public confidence” rationale described above, the Commission believes that public confidence in the renewal process would be adversely affected if the Commission were to allow the initiation of manufacture of a new reactor after the expiration of the manufacturing license. Accordingly, the Commission declines to adopt the commenter’s suggested change to § 52.173, and no change to the final rule has been made in this regard as the result of the comment.

Comment 005-28: The commenter stated that on p. 12807, in the discussion of the specification of “earliest and latest” dates for COLs and MLs, it is not clear why these are required for an ML. Since the ML is issued for a fixed term, the date of issue and date of expiration would appear to establish those criteria. For a COL, the NRC does not state if it is possible to modify the “latest date” for completion of construction. If it is not possible to do so, this requirement would appear to be meaningless, since it would encourage a COL applicant to specify a date sufficiently far in the future to preclude the possibility of forfeiting the license because of unforeseen delays.

NRC Response: The Commission agrees with the commenter. As discussed in the SOC for the proposed rule (71 FR at 12801, third column), the Commission is not specifying an earliest and latest date for completion of manufacture. The SOC discussion at p.12807 is incorrect, inasmuch as proposed § 50.55a(a) and (b) did not specify that a manufacturing license is subject to the condition that the earliest and latest date of manufacture be specified. This discussion has been deleted from the SOC for the final rule.

Changes to Manufacturing License

Comments 007-49 and 005-25: Several commenters noted that proposed § 52.171(b)(1) would not allow the holder of a manufacturing license to make changes, except by means of a license amendment. The commenters also noted that the Supplementary Information for the proposed rule states that the “NRC proposes to provide a greater degree of finality to a manufacturing license,” and that “one of the key reasons for licensing manufactured reactors is to enhance standardization.” The commenters continued to note that the NRC also suggests that allowing changes could result in losing the advantages of a manufactured reactor if each one is treated as a “one-off” custom product.

The commenters stated that the need for NRC approval of every change to a manufacturing license that may be identified is not justified. The commenters asserted that, on the contrary, a manufacturer can maintain the concept of a standard design when making relatively minor

⁵The Commission notes that the final License Renewal Rule established a 5-year period for timely submission of a renewed operating license application. However, as indicated in the SOC for the final rule, the 5-year period was established to be consistent with the Commission’s decommissioning rules which require submission of decommissioning plans and related financial assurance information about 5 years before expiration of the operating license. See 56 FR at 64962 (third column).

changes in procurement, manufacturing, and quality assurance processes, as allowed by or consistent with the 10 CFR 50.59 change process. The commenters suggested that the manufacturer would periodically report these changes to the NRC and the change processes would be subject to NRC oversight.

In this regard, the commenters stated that there is no greater need for standardization of reactors fabricated under a manufacturing license versus reactors constructed under a design certification. The commenters noted that, as provided in 10 CFR 52.63(b)(2) and Section VIII.B.5 of the design certification rules, a COL holder or applicant may depart from a design certification using a § 50.59-like process. The commenters asserted that this same flexibility should be afforded to the holder of a manufacturing license.

One of the commenters also noted, given experience to date in which changes to certified designs are being requested by prospective COL applicants, it is not clear why the NRC believes that the situation would be any different for a “manufactured” reactor. Moreover, the commenter stated that by “freezing” the design under a manufacturing license for up to 15 years, the NRC stifles innovation and improvements that could improve safety and reliability. The commenter noted that while enhancement of standardization is a worthy goal, there are circumstances in which advancement of technology and improvement of safety demand departures from a standard approach. The commenter stated that this provision of the NRC’s rules ignores that fact.

The commenters stated that it simply is not realistic to expect zero changes in a reactor design over a 15-year period. The commenters noted that, due to factors such as obsolescence of components and changes by component suppliers, minor changes should be expected. The commenters stated that it would pose an undue burden on the holder of the manufacturing licensee and the NRC to require such minor changes to be subject to prior NRC review and approval.

NRC Response: The Commission does not agree with the commenters that the design of a manufactured reactor should be subject to less-stringent change provisions (e.g., the use of 50.59 for all portions of the design to be manufactured) than a standard design certification. The commenters have not demonstrated that there are special or unique aspects of manufacturing, as compared with construction of nuclear power plant based upon a referenced standard design certification, that would weigh against maintaining the high degree of design standardization achieved by design certification. Hence, the Commission believes that - similar to requirement for design certification changes to be accomplished by rulemaking - changes to the approved design in a manufacturing license should be accomplished in all cases through license amendments.

One commenter correctly noted that changes in such manufacturing matters as procurement, manufacturing processes, or quality assurance are not subject to the proposed § 52.171(b)(1) change restriction, because these matters do not constitute changes to the approved design of the reactor to be manufactured. Such matters may be changed in accordance with applicable change process and restrictions already established in the Commission’s regulations (e.g., § 50.59, 50.54(a)), and may not require license amendments.

The Commission does not agree with the commenter who argued that a requirement for license amendment to change the approved design in a manufacturing license would stifle innovation

and safety improvements. It is unclear why the need to obtain NRC approval via a license amendment would prevent a manufacturing license holder from seeking changes which are innovative or safety-enhancing.

Thus, the only relevant rationale provided by the commenters is that obsolescence of components and component manufacturers' changes would necessitate minor changes to the reactor design over 15-year period. Although the Commission acknowledges the likelihood of these factors, we do not see any reason why these factors are more likely to affect the design of a manufactured reactor as compared with the design approved in a design certification; indeed, it is not even clear why a change in component sourcing would necessarily result in a "design change" requiring an amendment to the manufacturing license. Finally, the Commission notes that the proposed rule does not mandate "zero changes in a reactor design." As specifically stated in the SOC, 71 FR at 12801 (second column), proposed § 52.171(b)(1) would allow the manufacturer to make changes to the approved design to be manufactured, albeit by license amendment.

The Commission does not agree with one commenter's proposal to allow a holder of a manufacturing license to change the approved design under the § 50.59 change process. The commenter's assertion, that § 52.63(b)(2) and Section VIII.B.5 of the four standard design certification rules approved to date allow a COL holder to depart from a referenced design certification, is misleading. The VIII.B.5 change process applies only to "Tier 2" changes which are not "certified." The § 52.63(b)(2) process provides for plant-specific departures from Tier 2 of the standard design, i.e., the approved design itself is not being changed, and the departures permitted by rule are limited to Tier 2. By contrast, the "Tier 1" portion of the design which is "certified" is subject to the much more stringent change standards in § 52.63(a). As stated in the SOC, the Commission wishes to maintain a high degree of standardization in manufacturing licenses as well.

For these reasons, the Commission declines to adopt the commenters' suggested changes, and no change to the final rule has been made as the result of this comment.

"Economic Risk" is Not an Appropriate Justification for Changes to Regulations on MLs

Comment 005-24: A commenter stated that it is not clear to their organization why the NRC is using "economic risk" arguments as a basis for proposing changes to Appendix M on manufacturing licenses. [See 71 FR 12800] The commenter noted that aside from the fact that the capability of the NRC to anticipate economic impacts to potential applicants is open to question, this has in the past not been a criterion that the NRC has employed to determine the necessity of changes to regulations. The commenter recommended that the NRC limit its considerations for making changes to Part 52 and related regulations to those associated with public health and safety, along with the need to provide clear and unambiguous regulatory requirements. The commenter stated that "economic risk" should be an issue left to industry assessment.

NRC Response: The Commission believes that the commenter misunderstood the Commission's argument in this regard. The Commission was suggesting that the economic incentives and limitations for approval of a final design for manufacture, are the same as those faced by applicants for standard design certifications. Inasmuch as there continues to be

interest in design certification by potential design certification applicants, the Commission believes it is reasonable to conclude that a requirement for a final design in a manufacturing license is neither unreasonable nor economically impracticable.

The Commission disagrees with the commenter's suggestion that the Commission should limit its consideration for Part 52 changes to those associated with public health and safety. The commenter's suggestion ignores the Commission's statutory responsibility to address common defense and security as well as radiological health and safety. More importantly, the commenter's suggestion precludes the Commission from considering and adopting some of the significant changes sought by nuclear power industry stakeholders in the Part 52 rulemaking, which are not based upon radiological health and safety concerns but by considerations of economics, regulatory efficiency, and reduction of unnecessary regulatory burden. One example would be stakeholder suggestions that the Commission modify § 52.79 to allow design certification rules to be amended to incorporate changes resulting in significant improvements in efficiency or economics. See NEI May 30, 2006 comment letter, at p. 20-23; Westinghouse comment letter, at p. 4. If the commenter's position were adopted by the Commission, the Commission would be unable to consider or adopt such changes. Nor would the Commission be able to identify, on its own initiative, potential rulemaking changes - such as the changes proposed for the manufacturing licenses - which reduce unnecessary regulatory burden while maintaining or enhancing public health and safety or common defense and security.

In any event, the commenter did not identify any fundamental problem with the Commission's proposed changes to the manufacturing license requirements in Part 52. Accordingly, no change was made in the final rule as the result of this comment.

Conditions Under Which Manufacturing License Will be Granted

Comment 005-26: A commenter recommended that the NRC should clarify the conditions under which an NIL can be granted. The commenter also asked if manufacturing licenses are only for reactors that are small enough to be built offsite and transported essentially as a single unit to another location for installation, or would it be possible for a manufacturing license to be granted for the manufacturer of a large plant that would be transported to its site in sections or "modules" for installation.

NRC Response: The Commission's concept for a manufacturing license under Subpart F is the same concept that was originally adopted in Appendix M of Part 50, and transferred to Appendix M of Part 52, viz., the license would approve the manufacture of an entire nuclear power reactor to be transported as single unit from the location of manufacture to the ultimate site of the nuclear power plant. This is clearly reflected in the language of §§ 52.151 and 52.153.

The Commission considered adopting a regulatory approach for manufacturing licenses that would allow approval of the manufacture of modules or sections for a single large reactor at a manufacturing location, to be transported to another site where the modules or sections would be "assembled/integrated into a single working nuclear power plant. However, the Commission decided against extending the manufacturing license concept in this rulemaking to such modular or sectional manufacture, for several reasons. First, the concept represents a significant extension beyond the current manufacturing license concept, and constitute a

substantial extension of the concept of “manufacture” for which a manufacturing license is necessary under Section 185 of the AEA. Second, the extension of the NRC’s jurisdiction to the “manufacture” of modules and section, and its policy and legal ramifications, had not been discussed with external stakeholders during the Part 52 rulemaking development process. Although the concept of approving a final design for a manufacturing license was not discussed with external stakeholders during the rulemaking process, the Commission believed that this proposal was a logical extension of the principles underlying Part 52, in particular, early resolution of design issues. By contrast, requiring a license for the “manufacture” of modules or sections of a plant, raises issues regarding the regulatory need for licensing of other activities that could be regarded as “manufacturing,” viz., the fabrication of components. The Commission is not adverse to the commenter’s proposal; it is both the timing of the proposal and the value of greater public interaction with stakeholders that are of Commission concern. If there is interest in developing the concept, the commenter and/or interested stakeholders may submit a petition for rulemaking.

5.3.7 Subpart G - Enforcement

No comments received.

5.3.8 Design Certification Rules

Comment 005-12: The commenter noted that on page 12808, in its discussion of 10 CFR 50.59, the NRC states that when a COL references a DC rule, the change processes for a design control document (DCD) incorporated in that rule are controlled by what is specified in the DC rule. This discussion helps to illuminate a troubling element of Part 52, particularly after a plant begins operation. The NRC has, over the years, evolved a process for making changes in operating plants, as controlled by the appropriate sections in 10 CFR Part 50 (including, but not limited to, 10 CFR 50.59), and associated regulatory guidance. It is possible, however, for plants licensed under Part 52 to be subject to new rules that establish a new, parallel process governing such changes, including (but not limited to) the Tier 1 and Tier 2* requirements in DC rules that are supposed to apply for the life of the plant. In light of the evolution of technology over the period for which these plants are designed to operate (60 years or more) it is not clear why it is necessary to restrict changes in such a fashion. This is another case in which the goal of “standardization” is apparently raised above any other aspect of plant design and operation, including that of safety. The commenter indicated that the policy governing changes in various aspects of plant design and operation (e.g., fuel design criteria included in Tier 2* DC rules) imposes an additional, undue burden on Part 52 licensees where those requirements exceed those imposed on Part 50 licensees. The commenters recommended that, for those aspects of plant design and operation for which Part 50 controls exist, the NRC should employ those controls rather than establish a parallel process in Part 52.

NRC Response: The NRC does not agree with this comment. As stated in § 52.98(c), if the combined license references a certified design, then changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule. This requirement supports the goal of achieving and maintaining the safety benefits of standardization, which both NRC and the nuclear industry support.

Clarification of Severe Accident Change Process for Departures from Tier 2 of Design Control Document

Comment 007-10: Several commenters noted that the proposed rule includes modifications to Section VIII.B.5.c of each of the appendices to Part 52 for design certification. This section of the design certification rule specifies the process for determining whether or not a license amendment is required for a departure from Tier 2 affecting resolution of a severe accident issue. The proposed changes to Section VIII.B.5.c are currently limited to modifying the introductory language to conform to 10 CFR 50.59 terminology (i.e., it would delete references to “unreviewed safety question” and “safety evaluation”).

The commenters stated that clarification is needed in the rule language both for consistency with the terminology in 10 CFR 50.59 and to conform to the Commission’s intent for this section of the rule, as explained in the Statement of Considerations for each of the design certification rulemakings. The commenters quoted the Westinghouse AP1000 final rule, the Commission’s purpose for Section VIII.B.5.c. [See 71 FR @ 4462, 4474, Jan. 27, 2006.]

In addition, the commenters noted that during a public meeting with the NRC on April 18, 2006, the NRC clarified that the change process in Section VIII.B.5 of the design certification rules was not intended to apply to discussions of the probabilistic risk assessment in Tier 2. The commenters believe that this is an important clarification that should be reflected in the design certification rules so that the rule language is not misconstrued.

NRC Response: The NRC does not agree that the rule language in Section VIII.B.5 of the design certification rules (DCRs) needs to be clarified as proposed by NEI. The NRC believes that the SOC for each of the DCRs provides sufficient explanation for this provision. Also, because the rule clearly applies to departures from severe accident design features, rule language is not needed to state that the severe accident change process is not applicable to the probabilistic risk assessment in Tier 2.

5.4 Changes to 10 CFR Part 50

5.4.1 50.1-50.9 General Provisions

No comments received.

5.4.2 50.10-50.13 Requirement of License, Exceptions

Support for Limited Work Authorizations (LWAs)

Comments 004-1, 004-2, 004-3, and 004-26:⁶ The commenters supported the Limited Work Authorizations process that were promulgated by the NRC in the past. The LWA allows for the applicant to conduct certain activities in parallel with the NRC’s licensing process and before issuance of a COL. The commenters emphasized that minimizing licensing time is critical for

⁶Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI’s comments submitted on May 25, 2006. Therefore, all of these commenters are included in each of NEI’s May 25, 2006 comments (comment number 004). For simplicity, these comment numbers are not repeated in this document for each comment.

prospective COL applicants to reduce schedule time and costs. The specific “pre-construction” activities that new plant applicants may need to initiate will be both site-specific and technology-dependent to a certain extent. Additionally, commencement of certain pre-construction activities in parallel with the NRC licensing process will mitigate schedule impacts occasioned by placement of a new nuclear facility on a site with a currently operating reactor.

NRC Response: The Commission is proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. These revisions to the LWA process will contribute to minimizing NRC licensing time, and will allow entities to commence pre-construction activities in parallel with the NRC licensing process.

The NRC should not overstep its jurisdiction under AEA and NEPA.

Comments 004-6 and 004-14: The commenters argued that NRC’s authority is “confined to scrutiny of and protection against hazards of radiation” as found in *New Hampshire v. AEC*, 406 F.2d 170, 175 (1st. Cir 1969), cert. denied, 395 U.S. 962 (1969), see also *Gage v. AEC*, 479 F.2d 1214, 1221 n.19 (D.C. Cir. 1973). They said the Commission lacks the authority to mandate that an applicant take certain actions that are unrelated to radiological considerations.

NRC Response: The NRC agrees with the comment.

NRC should revise regulations regarding construction and LWAs

Comment 007-28: The commenters found that the proposed § 50.10(e)(3) would continue to restrict safety-related construction activities that could be conducted prior to issuance of a COL to the installation of structural foundations, including any necessary subsurface preparation. The commenters proposed that the NRC amend its regulations to specifically allow a COL applicant that references a design certification to conduct any construction activity approved as part of the design certification.

NRC Response: The NRC agrees with the comment. After consideration of the public comments on limited work authorizations (LWAs), the Commission is proposing to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule.

Comments 004-4, 004-6, 004-7, 004-9, 004-10, 004-11, and 004-13: The commenters stated that the definition of “construction” reflected in 10 CFR 50.10(b) is based on the correct interpretation of the NRC’s responsibility under the Atomic Energy Act and is consistent with the agency’s NEPA obligations. The commenters noted that while the license requirement in § 101 of the AEA does not specifically identify “construction” of a utilization facility as an activity requiring a license and § 185 of the Act describes construction permits and COLs, 42 U.S.C. § 2235, it does not prohibit “construction” directly. See *supra*, § I.A. The commenters questioned what constitutes “construction” for which a prior NRC license is required.

NRC Response: The NRC agrees with the comments. The Commission is proposing to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule.

Comments 004-4, 004-6, 004-7, and 004-13: The commenters argued that the restrictions on the “commencement of construction” under § 50.10(c) are at odds with § 50.10(b).

The commenters point out that neither the AEA itself nor any legislative history attempts to define “construction” (or otherwise define the point at which the licensing requirement is triggered) and they cite Carolina Power & Light Co. (Shearon Harris Nuclear Power Plant, Units 1, 2, 3, and 4), CLI-74-22, 7 AEC 939 (1974). The commenters noted that the 10 CFR 50.10(b); 25 FR 8712, September 9, 1960) NRC regulations concluded that “construction” included pouring the foundation for, or the installation of, any portion of the permanent facility on the site. However, the commenters noted that the “newer” regulations state that, notwithstanding the activities permitted under § 50.10(b), no person shall effect “commencement of construction” without a permit.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-14: The commenters stated that the definition of “construction” in 10 CFR 50.10(b) is fully consistent with the requirements in § 185 of the AEA. The pre-licensing, pre-construction elements listed in §§ 50.10(b) and 50.10(e)(1) involve site-preparation and logistical support and, as such, do not involve making or forming devices or equipment capable of using special nuclear material that are prohibited without an NRC construction permit. The intent of Congress in the AEA is clear and unambiguous: “construction” can only mean activities related to assembling devices capable of utilizing special nuclear material. (See New Hampshire, 406 F.2d at 175). Thus, the Commission’s original interpretation of “construction of a utilization facility” referenced in § 50.10(b) is reasonable and entitled to considerable deference. See *Chevron*, 467 U.S. at 844-845; see also, *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference due to agency depends on, among other things, the consistency of the agency’s position).

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission is proposing to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comments 004-4, 004-8, 004-9, and 004-14: The commenters noted that the restrictions on the “commencement of construction” in § 50.10(c) and the prohibitions on pre-licensing activities in § 50.10(e)(1) are unnecessary under NEPA and relevant statutes. The commenters recommended these be deleted in order to align NRC regulations with an evolved understanding of an agency’s role under NEPA case law that post-dates existing § 50.10(c). Further, the commenters argued that in contrast with the reasonable interpretation of “construction” in § 50.10(b), 10 CFR 50.10(c) establishes an inexplicably circular definition of “commencement of construction.” Activities in the definition of “commencement of construction” include activities that are not “construction” under § 50.10(b) and do not require a construction

permit. Logically, however, if activities are not “construction” under § 50.10(b), they should not be “commencement of construction” under § 50.10(c). If an activity does not fall within the definition of construction under § 50.10(b) and does not require a construction permit under § 185 of the AEA, prior NRC approval of that activity should not be necessary under the AEA.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopting substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 007-29: The commenters request that NRC clarify that pre-construction activities include manufacturing of modules. The commenters recommended that § 50.10(b) continue to allow the procurement or manufacture of components of the facility prior to issuance of a CP or COL. The commenters further suggested that the Part 52 final rule should clarify (possibly in the Supplementary Information provided by the Commission) that this exclusion applies to the procurement and manufacturing of Part 52 facility construction modules, and that a CP or COL applicant may procure or manufacture construction modules.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NRC should allow for an accelerated LWA-2 process.

Comments 004-5 and 004-22: The commenters recommended that LWA-2 findings be accelerated based on the applicant submitting a partial environmental analysis, a partial environmental review by the staff, and related findings by the NRC Atomic Safety and Licensing Board focused only on the impacts of specific proposed LWA-2 activities. The commenters alternatively recommended that the Commission could remove the requirement that the presiding officer make environmental findings for LWA-2 activities and authorize the staff to make those findings instead. See *Union of Concerned Scientists v. U.S. Nuclear Regulatory Commission*, 920 F.2d 50, 56 (D.C. Cir. 1990) (“While NEPA clearly mandates that an agency fully consider environmental issues, it does not itself provide for a hearing on those issues.”)

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-22: The commenters stated that issuance of an LWA-2 based on focused environmental findings would be acceptable under NEPA and that the NRC has successfully employed similar processes on prior occasions. The commenters stated that the NRC could separately consider different segments of a proposed project. See *Tennessee Valley Authority (Clinch River Breeder Reactor Plant)*, CLI-82-23, 16 NRC 412, 424 (1982) (noting that separate

consideration of different segments of a project is “well-established”). The NRC could also authorize an individual, sufficiently distinct, portion of an agency plan without awaiting the completion of a comprehensive environmental impact statement so long as the environmental treatment under NEPA of the individual portion is adequate and approval of the individual portion does not commit the agency to approval of other portions of the plan. [See *Kerr-McGee Corp. (West Chicago Rare Earths Facility)*, CLI-82-2, 15 NRC 232, 265 (1982), *aff’d sub nom. City of West Chicago v. NRC*, 701 F.2d 632 (7th Cir. 1983); *Peshlakai v. Duncan*, 476 F. Supp. 1247, 1260 (D.D.C. 1979); *Conservation Law Foundation v. GSA*, 427 F. Supp. 1369, 1374 (D.R.I. 1977).] Further, the NRC is not responsible for ensuring that the applicant has received the appropriate state, local, or federal permits needed to perform LWA activities. See *Public Service Co. of Oklahoma (Black Fox Station, Units 1 & 2)*, LBP-78-26, 8 NRC 102, 123, 129 (1978) (holding that applicants are not required to have every permit in hand before a LWA is granted).

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-25: The commenters stated that with respect to any hearing on LWA-2 issues, the presiding officer may conduct separate hearings and issue separate partial decisions on issues pursuant to NEPA, on general site suitability issues specified by 10 CFR 50.10(e), and on certain limited work authorization issues. *United States Department of Energy et al. (Clinch River Breeder Reactor Plant)*, LBP-83-8, 17 NRC 158, 161 (1983), vacated as moot, ALAB-755, 18 NRC 1337 (1983). Separate LWA and COL hearings are simply separate phases of the same proceeding. *United States Department of Energy et al. (Clinch River Breeder Reactor Plant)*, ALAB-761, 19 NRC 487, 492 (1984). The Commission may therefore appropriately direct the presiding officer, where appropriate (or requested by an applicant), to consider bifurcating, and conducting separately, the COL and LWA-2 portions of a proceeding. Accordingly, the NRC should take the steps necessary to enhance the LWA-2 process.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 007-28: The commenters recommended that NRC regulations be modified to allow the applicant to propose and justify specific site preparation activities in advance of the submittal of its complete licensing documents to the extent that ESP holders or COL applicants seek to conduct LWA-2 activities. This focused request would be subject to an appropriately focused and expedited staff review and a limited hearing, resulting in the issuance of an expedited licensing board decision on the specific LWA-2 activities requested. The applicant would submit a full environmental report, and the staff would issue a full EIS and hold related hearings, on a less accelerated schedule.

NRC Response: After consideration of the public comments on limited work authorizations

(LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NRC should allow pre-construction activities without permits or LWAs

Comments 004-4, 004-8, 004-12, and 004-18: The commenters recommended that NRC modify its regulations to allow applicants to conduct the pre-construction activities contemplated by § 50.10(b) and 50.10(e)(1) without a prior NRC permit or an LWA. NRC approval of pre-construction activities should focus solely on matters pertaining to safety.

The commenters noted that certain activities are permissible even without an exemption to § 50.10(c) or an LWA (e.g., upgrading existing access roads, drilling exploratory borings, clearing trees, etc.). The NRC allows pre-LWA activities to be undertaken by an applicant if those activities would have a “trivial” environmental impact. Kansas City Gas and Electric Co. (Wolf Creek Nuclear Generating Station, Unit No. 1), CLI-77-1, 5 NRC 1, 12 (1977). The decisions on *de minimis* impacts stress that triviality in this context does not mean “zero” impact, but instead means impacts for which it can “safely be said that no conceivable harm would have been done to any of the interests sought to be protected by NEPA should the eventual outcome of the proceeding be a denial of the application.” [Puget Sound Power & Light Co. (Skagit Nuclear Power Project, Units 1 and 2), ALAB-446, 6 NRC 870, 871 (1977); see also, Washington Public Power Supply System (Nuclear Project Nos. 3 and 5), CLI-77-11, 5 NRC 719, 723 (1977).]

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NEPA does not expand NRC's licensing requirements or jurisdiction.

Comments 004-15 and 004-16: The commenters argued that revising the construction and LWA regulations would leave the NRC still fully compliant with its NEPA responsibilities and would not expand NRC licensing requirements. As a procedural statute, NEPA cannot impose licensing or permitting requirements on a private applicant more stringent than those authorized by the safety provisions of the AEA. [Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989).] The commenters stated that the NRC's current regulations that impose substantive licensing requirements and related environmental obligations on activities that do not require a construction permit, are “inconsistent with NEPA's reliance on procedural mechanisms” and the statute's focus on federal actions. The commenters suggested that the NRC may have taken its obligations under NEPA further than necessary (see Hartsville, 5 NRC at 576) in that while the NRC is obligated under NEPA to consider non-radiological environmental impacts from construction and operation as part of its licensing process, NRC may not prohibit (or require prior NRC approval of) activities that do not entail construction under § 50.10(b) and do not require a construction permit under AEA § 185. The commenters acknowledged that indirect or non-radiological impacts of federal actions would still need to be

reviewed in an environmental impact statement when a federal action becomes involved (i.e., when the licensing requirement of the AEA is triggered). The commenters stated that NEPA does not expand the jurisdiction of or mandate action beyond the agency's organic statute [Gage, 479 F.2d at 1221 n.19; Kitchen v. FCC, 464 F.2d 801 (D.C. Cir. 1972)], and further NEPA does not impose requirements more stringent than those contained in the safety provisions of the AEA. [Philadelphia Electric Co. (Limerick Generating Station, Units 1 and 2), ALAB-819, 22 NRC 681, 696 n.10 (1985) citing Public Service Electric & Gas Co. (Hope Creek Generating Station, Units 1 & 2), ALAB-518, 9 NRC 14, 39 (1979); see also, Methow Valley, 490 U.S. at 347 (1989).]

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comments 004-17: The commenters argued that because pre-licensing site preparation activities are undertaken by private, not federal, entities, they do not require a separate NEPA review when taken on their own. Thus, the commenters suggested that if the activity does not require a construction permit, then NEPA does not require the Commission to prohibit the activity pending NRC review and approval. NRC should not require a construction permit for the pre-licensing activities. The commenters cited the Council on Environmental Quality (CEQ) regulations 40 CFR § 1506(b) and *New Jersey v. Long Island Power Authority*, 20 F.3d 284, 293 (1st Cir. 1995). The commenters acknowledged that while the NRC must assess the environmental impacts of its action, including the indirect impacts and impacts of connected, similar, and cumulative actions, the agency's ability to require prior approval or coerce action only extends to those matters for which approval is required by the AEA.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-18: The commenters stated that an agency's jurisdiction is limited to that granted by its organic statute. (Gage, 479 F.2d at 1221 n.19; Kitchen, 464 F.2d at 801). The courts have not enjoined private action under NEPA where the activities fell wholly outside the permitting jurisdiction of an agency. [See e.g., *North Carolina v. City of Virginia Beach*, 951 F.2d 596 (4th Cir. 1996) (allowing continued construction by non-federal entity since a federal agency's environmental review of project was binding only on those aspects that were within the jurisdiction of the agency, even if the agency elected to analyze under NEPA those portions of the project that were beyond its control).]

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NEPA Analysis of pre-licensing activities does not constitute segmentation under NEPA.

Comments 004-19 and 004-20: The commenters stated that where a COL applicant seeks to perform pre-licensing activities, there is but a single federal action - the granting or denial of the COL - whose impacts must be considered under NEPA and that this does not constitute segmentation under NEPA as defined in 40 CFR §§ 1508.7, 1508.8, and 1508.25. Thus, even if the NRC considers the private and federal actions together for NEPA purposes, there is no segmentation since the pre-licensing activities are not “connected” to the NRC’s decision on a COL application. The commenters stated that it is neither “unwise” or “irrational” to complete the pre-licensing activities apart from a COL since those activities merely preserve the option of later COL construction. [Webb, 699 F.2d. at 161; South Carolina v. O’Leary, 64 F.3d 892, 899 (4th Cir. 1995).] Since a COL applicant would be undertaking redressible, pre-licensing actions at its own risk and without expenditure of federal funds, there is no chance of those private actions directly influencing the Commission’s decision on whether the COL should be issued. Therefore, there can be no segmentation as there are no “connected actions.”

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Consideration of indirect actions under NEPA are not grounds for requiring additional environmental analyses for licensing activities.

Comments 004-21, 004-23, and 004-24: The commenters stated that while it might be argued that the pre-licensing activities could affect the ultimate NEPA weighing and balancing of environmental considerations or limit consideration of reasonable alternatives and thus the NRC should require additional NEPA analysis for pre-licensing activities, this argument would not provide a basis for the NRC to prohibit purely private action that does not require a construction permit under the AEA. The commenters noted that the pre-licensing and pre-construction impacts would simply be considered during the overall NEPA evaluation of the subsequent federal action. Moreover, even if NEPA could prevent such private action, the applicant’s at-risk activities are remediable and, in all likelihood, would be addressed in the required site redress plan. Likewise, those pre-construction activities would still be subject to applicable stated and local permits and the related review processes.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NRC should not adopt regulations that would limit allowable pre-construction activities.

Comment 007-28: The commenters stated that proposals that would limit allowable pre-construction activities should not be adopted by the NRC. The commenters stated that the proposed rule contains new requirements that place unnecessary new limits and burdens on

COL applicants and ESP holders that wish to obtain Limited Work Authorizations (LWAs) and perform pre-construction site preparation activities. For example, the current rule contemplates that an ESP holder may conduct site preparation activities authorized by § 50.10(e)(1) without specifically listing or restricting the activities that could be performed. Under the current rule, a COL applicant may request separate authorization to conduct the activities listed in § 50.10(e)(1) or § 50.10(e)(3)(i). The commenters found these proposed amendments even more restrictive and without justification. The commenters did not support these proposed changes, and recommended the solution outlined in the NEI May 25 submittal to allow applicants to conduct activities now categorized as LWA-1 activities without prior NRC review or approval of any kind.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 007-28: The commenters objected to the proposed § 50.10(e) because like the current regulation, it also appears unnecessarily restrictive in that it would continue to require issuance of an FEIS and issuance of Licensing Board findings as a prerequisite to performing LWA-1 site preparation activities. The commenters suggested that these requirements be eliminated. The commenters argued that there is no need for NRC to approve LWA-1 activities because those activities are not safety-related. Moreover, NEPA does not require hearings on environmental issues. The LWA-1 activities would be at the risk of the applicant and, if necessary, would be subject to site redress based upon the environmental findings of the Licensing Board on the application as a whole.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

5.4.3 50.20-50.23 Classification and Description of Licenses

No comments received.

5.4.4 50.30-50.33(a) Applications for Licenses, Form, Contents (general)

No comments received.

5.4.5 50.34-50.39 Applications for Licenses, Form, Contents (technical), Ineligibility of Certain Applicants

Comment 005-20: The commenter noted that the text in 10 CFR Part 50 refers to historical requirements or historical agency actions and recommends that the language be removed unless there is a valid purpose to the language.

NRC Response: This comment addresses outdated language in the existing rule text. Correcting rule text that does not relate to the Part 52 processes is outside the scope of this rulemaking. Thus, corrections of this type have not been made in this final rule.

Comment 007-53: Commenters recommended that the following sentence in proposed § 50.34 be deleted: “each applicant for a design certification, design approval, combined license, or manufacturing license under Part 52 of this chapter shall demonstrate compliance with the technically relevant portions of the requirements in paragraphs (f)(1) through (3) of this section.” The commenters argued that this provision is inconsistent with the provisions in existing § 52.47(a)(1)(ii) and proposed §§52.47(a)(17), 52.79(a)(17), 52.137(a)(17), and 52.157(e)(12), which state that paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v) are not applicable to such applicants.

NRC Response: The NRC agrees with the commenter in part. The NRC agrees that proposed § 50.34(f) is inconsistent with proposed §§52.47(a)(17), 52.79(a)(17), 52.137(a)(17), and 52.157(e)(12). However, the NRC does not agree that the references to applicants for design certifications, design approvals, combine licenses, or manufacturing licenses should be deleted from § 50.34(f). Rather, the NRC is making changes to § 50.34(f) in the final rule to make it consistent with the requirements in Part 52.

Comments 007-54, 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017: Commenters noted that the proposed §50.36a would require a COL holder to submit an annual report of effluent releases during the construction period. The commenters recommended that the regulation be amended to require the annual reporting only after the 10 CFR 52.103(g) finding and commencement of operation of the plant. The commenters argued that this would make §50.36a consistent with the current Part 50 regulatory scheme, in which the annual reporting requirement is effective only after an operating license is issued.

NRC Response: The NRC agrees that additional changes are needed to § 50.36a to indicate that a COL holder is not required to submit an annual report of effluent releases until after the Commission has made the § 52.103(g) finding. The final rule contains a change to the reporting provision in § 50.36a(a)(2) to address COL holders.

Comments 007-54, 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017: Commenters noted that § 50.36b could be interpreted as authorizing the inclusion of environmental conditions in a COL that are immediately effective, rather than effective after the NRC has issued its 52.103(g) finding. The commenters recommended that to be consistent with the intent of § 50.36b, the section should be revised to provide that the environmental conditions may only be applied to the period after the NRC has issued its 52.103(g) finding.

NRC Response: The NRC disagrees with the commenters recommendation that § 50.36b be revised to provide that environmental conditions may only be applied to the period after the NRC has issued its 52.103(g) finding. The Commission can place environmental terms and conditions on its permits and licenses and this was stated in the proposed rule in §§ 51.50(a), (b), and (c). The proposed rule stated that, in an application for a construction permit, an early site permit, or a combined license, the applicant shall identify “any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter.” The staff has

modified § 50.36b in the final rule to make this applicability clear.

Environmental Conditions Applied to an ESP

Comment 011-1: A commenter stated that the NRC should clarify whether environmental conditions can be placed on an ESP (similar to 50.36b). [See discussion on § 52.24 in Section C.4.d of the NOPR Supplementary Information, page 12,791.]

NRC Response: The Commission has the authority to include environmental terms and conditions in an ESP. Section 50.36b is revised in the final rule to make this clear.

5.4.6 50.40-50.49 Standards for Licenses and Construction Permits

Comments 005-15 and 007-25: The commenters stated that the proposed rule suggests that changes to 10 CFR § 50.46(a)(3) are necessary to ensure that the NRC is “notified of changes to or errors acceptable evaluation models” used in Part 52 licenses, design certifications or standard design approvals. [71 FR 12805] The proposed changes to 10 CFR 50.46(a)(3) would impose the reporting requirements of 10 CFR 50.46 on design certification and standard design approval applicants, during both the application process and following issuance of the design certification rule or standard design approval. However, the commenters found that there is no reason for the NRC to be made aware of changes or errors unless and until a design certification or a standard design approval is referenced in a COL, operating license, or ML application. If the design certification or design approval is never referenced in a license application, no regulatory action is warranted to change or modify the standard design.

Also, the proposed changes to 10 CFR 50.46(a)(3) would create an unnecessary burden on both the NRC and the industry. A COL, operating license, ML applicant referencing a design certification will be required to identify any change to or error in an accepted evaluation model upon submittal of an application that references a design certification or design approval. Therefore, the necessary notification (and remedial action if warranted) will be taken at that time. Requiring the applicant for design certification or design approval to make a similar notification would be redundant and unnecessary.

Finally, for design certifications, the proposed changes to 10 CFR 50.46(a)(3) are inconsistent with the concept that design certification is a rulemaking proceeding rather than a licensing proceeding. The design certification applicant may not be the ultimate vendor of the plant referenced in the license application. If the design certification applicant is not the vendor, the actual vendor (or other entity designated by the license applicant) will need to develop and maintain its own calculations and evaluations to satisfy the requirements in § 50.46. In such a case, any changes or errors by the design certification applicant would not be relevant to the COL, since the design certification applicant’s evaluation would not be the evaluation of record used by the COL applicant.

In this regard, the commenters argued that the proposed change would represent a fundamental shift in the regulatory philosophy behind the reporting requirement in § 50.46, which has always been applicable to licensees and license applicants. Imposing similar requirements on vendors would represent a substantial departure from the existing regulatory provisions, with no real benefit or value. Furthermore, since the licensee and license applicant

will still be required to make such reports, the proposed rule would require reports by two different entities regarding the same error or change, creating the potential for inconsistencies and confusion.

The commenters suggested that there is no reason to impose a reporting requirement on applicants for design certification or design approval while their applications are pending, because proposed § 52.6(a) will require the applicants to provide information to the NRC that is complete and accurate in all material respects. This obligation is broader than the obligation in § 50.46, and will require applicants to update and correct their applications to account for the type of information covered by § 50.46.

NRC Response: The NRC agrees with the commenters statement that the NRC does not need to be aware of changes or errors unless and until a design approval or design certification is referenced. As a result, the amended rule language for § 50.46(a)(3) has been revised to state that the applicant or holder of a design approval or the applicant for a design certification does not need to report the change or error until the design approval or design certification has been referenced in an application. This process is consistent with the new reporting requirements for 10 CFR Part 21. However, the NRC does not agree that the design certification applicant's evaluation would not be the evaluation of record used by the COL applicant referencing the certified design. Therefore, the design certification and design approval applicants need to report any change to or error in an acceptable evaluation model or in the application of such a model to the NRC and any applicant or licensee referencing the design approval or design certification regardless of whether that applicant is the selected vendor for the applicant or licensee that has referenced the design approval or design certification.

Comment 007-55: The commenters note that § 50.45 states that an application for a COL or COL amendment must meet the requirements in 10 CFR§ 50.21 through 50.38 and 50.40 through 50.43, as applicable. The commenters state that the proposed rule would relocate to Part 52 most of the requirements in 10 CFR§ 50.21 through 50.38 and 50.40 through 50.43 for a COL. However, under the proposed rule, § 50.34 is not applicable to COL applicants (except as provided in proposed § 50.45). Therefore, the proposed rule is not consistent in its treatment of COLs.

NRC Response: The NRC does not agree that most of the requirements in 10 CFR 50.21 through 50.43 were relocated to Part 52 in the proposed rule, but does acknowledge that most of § 50.34 was relocated to the contents of application section for each of the licensing processes in Part 52. Therefore, § 50.45 was revised to set forth the standards for review of an application to alter a facility after the Commission makes the finding under § 52.103(g) of this chapter. The standards for issuance of a combined license are set forth in § 52.97.

Comment 007-56: The commenters stated that the proposed changes to 10 CFR 50.49 would make the regulation applicable to COL applicants and holders. Section 50.49(d) would require a license applicant or holder to have an environmental qualification file for electrical equipment important to safety. Currently, such requirements are only applicable to an applicant or holder of an operating license. Similarly, proposed §§ 52.47(a)(11), 52.137(a)(11), and 52.157(e)(6) would require applicants for design certification, design approval, and manufacturing licenses to include the information required by § 50.49(d). The commenters found that at the time of submission of the applications, and during construction or manufacturing under a COL or

manufacturing license, the applicant/licensee may not have identified the specific electrical components to be installed in the plant, and therefore will not be able to establish qualification files for all applicable components. To be consistent with the intent of the existing rule (which is not applicable during construction), the proposed rule should be modified to indicate that the requirement for qualification files applies only at the time of the NRC's 52.103(g) finding. For the same reason, the commenters recommended that applicants for design certification, design approval, and manufacturing licenses should not be required to establish qualification files, since those applicants may not yet have identified the specific electrical equipment (i.e., make and model) to be installed in the plant.

NRC Response: The NRC agrees that applicants may not be able to establish qualification files, but applicants can provide the electric equipment list required by § 50.49(d). Therefore, the requirements in §§ 52.47, 52.137, and 52.157 have been revised to only require a list of the electric equipment that is important to safety. This amended requirement is consistent with the requirement in § 52.79 and the list can be provided at the time of the application. The verification that the electric equipment has been properly qualified will be done with ITAAC.

5.4.7 50.50-50.55, 50.56-50.58 Issuance, Limitations, and Conditions of Licenses and Construction Permits

Comment 005-19: The commenter stated that on p. 12807, in the discussion of 10 CFR 50.54, the NRC refers to “prerequisites to licenses.” Since a COL may reference a DC or ESP, or both, or neither, the commenter asked NRC to clarify the “prerequisites” to which it is referring.

NRC Response: The statement which the commenter refers to reads, “Conditions applicable to Part 52 processes which are either licenses or prerequisites to licenses, and do not address activities analogous to construction for which a construction permit license is required under the AEA, are proposed to be addressed in § 50.54.” It appears that this statement, as well as other statements in this section, do not reflect the actual rule text issued with the proposed rule. In the proposed rule, only combined licenses and operating licenses are addressed in § 50.54. Therefore, this section has been revised in the final rule to reflect the actual changes to the rule language in §§ 50.54 and 50.55.

Comment 006-8: The commenter expressed concern that certain the proposed changes to NRC regulations in the proposed rule would apply provisions that are applicable to licensees to applicants for design certifications, despite the fact that such design certification applicants are not afforded the protections accorded to licensees under the law. This represents a fundamental shift in the nature of design certification and the status of design certification applicants. Such a fundamental shift is inappropriate, is unfair to design certification applicants, and in many instances is not authorized by law.

During discussions leading to the adoption of Part 52, the commenter sought to allow designs to be certified either by license or rule. The commenter was concerned that design certification by rulemaking would not accord the proponent of a certified design the type of protection that would be accorded to a licensee if a design was licensed. In adopting final Part 52 rule, the NRC rejected the commenter's position of allowing certification either by rule or license. The NRC elected to permit design certification only by rulemaking. [54 FR 15375, April 18, 1989] Thus, applicants for certified design approvals did not become “holders” of a certified design,

and the protections afforded to licensees under the Atomic Energy Act and the Administrative Procedure Act were not provided to such applicants. All references to such an applicant for a certified design approval as a “holder” of the design were deleted when the final Part 52 rule was adopted.

The commenter recommends that all provisions in the proposed rule that would apply to applicants for design certification the requirements applicable to NRC licensees should be deleted.

NRC Response: The Commission disagrees with the commenter that the proposed rule’s imposition on the design certification applicant of new regulatory obligations represents a fundamental shift in the nature of design certification which is “inappropriate...and unfair....” The choice of rulemaking versus licensing in design certification ultimately represents the Commission’s choice of the regulatory vehicle for providing its approval of a final reactor design. While it is true that the regulatory vehicle chosen will determine the manner in which regulatory obligations are imposed, the technical, regulatory and policy bases for the regulatory requirements exist regardless of the regulatory vehicle. For example, take the issue of reporting of defects in engineering on a reactor design. The public health and safety need for prompt reporting to the NRC of such defects is the same regardless of whether the reactor design was submitted to the NRC for approval by license, or approval by rulemaking. That is why Section 206 of the Energy Reorganization Act of 1974, as amended, imposes reporting with regard to “any facility or activity which is licensed or otherwise regulated pursuant to the Atomic energy Act of 1954, as amended...(emphasis added).” The Commission rejects as untenable any argument that a rulemaking “imposing” the legal obligation of design certification applicants to report defects represents a “fundamental shift” in the nature of design certification.

The commenter did not identify the protections which are afforded to licensees under the AEA and APA but are not provided to design certification rulemaking applicants. Therefore, it is difficult for the Commission to address the commenter’s concerns. The one matter of which the Commission is aware of a difference between rulemaking versus licensing, is the protection of proprietary information. In a licensing proceeding proprietary information may be protected from disclosure in accordance with the applicable provisions of the Freedom of Information Act (FOIA). FOIA’s protections for proprietary information do not extend to information in a rule, or forming the bases for a rule; such information must ordinarily be disclosed in a rulemaking proceeding. However, this matter was thoroughly considered and addressed in the 1989 Part 52 rulemaking, and nothing in the 2006 proposed rule changes alters the Commission’s prior consideration of this issue with respect to design certification rulemaking. Moreover, although the commenter argues that “some of the proposed changes” are “not authorized by law,” the commenter does not identify the specific changes in the proposed rule falling into this category, which makes it impossible for the Commission to address the commenter’s concern on a specific basis. Nor does the commenter present any argument in support of this assertion or otherwise address the Commission’s discussion in the SOC for the proposed rule in which the Commission identified the statutory bases for the most significant obligations imposed on design certification applicants, namely, Parts 19 and 21.

For these reasons, the Commission has not made any changes to the final rule in response to the commenter’s suggestion.

New Requirements for an Applicant for an ESP or Design Certification to Describe its Quality Assurance (QA) Program

Comment 007-37: The commenters objected to the broad application of Appendix B requirements. As written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program. The commenters recommended that these provisions be revised to clarify that the Appendix B quality assurance program applies only to activities affecting the safety-related functions of the structures, systems, and components, and not to all ESP site activities, design activities, and construction activities. The recommended changes would make these new Part 52 requirements consistent with existing Appendix B, which states, “The pertinent [QA] requirements of this appendix apply to all activities affecting the safety-related functions [of SSCs].”

The commenters stated that the proposed changes to Appendix B could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B. Not all of those criteria are applicable to each of the applicants. For example, Criterion III on design control, Criterion IX on special processes, and some of the other criteria are clearly inapplicable to ESP applicants. Similarly, Criterion IX, Criterion X on inspections, and some of the other criteria would not be applicable to applicants for design certification and design approval. The commenters recommended that the language be modified to clarify that the applicant need only establish and implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant.

NRC Response: The NRC does not agree that, as written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program, as opposed to applying only to activities affecting the safety-related functions of the structures, systems, and components. The commenter quoted the following words from the existing language in Appendix B, “The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components,” [emphasis added], as evidence that the existing requirements relate only to safety-related SSCs. These words have not been removed from Appendix B and therefore apply to all of the new Appendix B requirements for ESPs, design certifications, design approvals, and manufacturing licenses. The NRC notes that the requirements in the current versions of §§ 50.34(a)(7) and 50.55(f) applicable to construction permits do not contain qualifiers that the Appendix B QA requirements apply only to activities affecting safety-related SSCs because such a qualifier is unnecessary given the language in Appendix B to Part 50. In creating parallel requirements for the Part 52 licensing and approval processes, the NRC tried to be as consistent as possible with the existing requirements for Part 50 applicants and licensees.

NEI also commented that some of the proposed language regarding QA requirements could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B and noted that not all of those criteria are applicable to each of the applicants.

The NRC does not agree that the proposed rule language regarding QA requirements for an ESP, design certification, design approval, or manufacturing license needs to be modified. Each of the subject provisions (52.17, 52.47, 52.137, and 52.157) states that the description of the quality assurance program must include a discussion of how the applicable requirements of Appendix B will be satisfied [emphasis added]. Therefore, the NRC believes it is clear that it was not the intent to apply the Appendix B requirements too broadly and that the language in the proposed rule is sufficient to indicate that the applicant need only implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant. Therefore, no changes have been made to these sections in the final rule.

Note that on July 19, 2006, the commenter (NEI) informed the NRC by e-mail (ML062710327) that it could not recreate the basis for some of the words in its May 30, 2006 recommended language for 52.17(a)(i)(xii) and that, for purposes of dispositioning this comment, the NRC should ignore them.

Comment 007-57: The commenters stated that the proposed rule would make 10 CFR 50.54 applicable to COLs. Currently, § 50.54 applies only to plants in operation, and is not applicable to plants under construction. To be consistent with this regulatory intent, not all of the provisions in § 50.54 should be applicable to COLs during construction. The commenters recommended that the following provisions in § 50.54 should not be applicable to a COL prior to the time of the 52.103(g):

- (1) 50.54(i), (j), (k), (l), (m), which apply to control room operations
- (2) 50.54(i-1), which applies to operator requalification programs
- (3) 50.54(o), which pertains to containment leak rate testing
- (4) 50.54(p), (q), and (t), which pertain to preparing, maintaining, and/or implementing certain plans
- (5) 50.54(w), which establishes insurance requirements
- (6) 50.54(z), which establishes reporting requirements.

NRC Response: The NRC agrees in part with the commenters. The NRC agrees that not all of the provisions in § 50.54 should be applicable to COLs during construction. However, the NRC does not agree that the provisions in paragraphs (o), (p), and (q) should not be applicable during construction. Paragraph (o) basically requires licensees to comply with Appendix J. Although currently, § 50.54(o) is applicable to operating licensees after the license is issued, Appendix J contains preoperational test requirements. Appendix J requires that preoperational testing requirements be implemented upon completion of construction of the primary reactor containment, including installation of all portions of mechanical, fluid, electrical, and instrumentation systems penetrating the primary reactor containment pressure boundary, and prior to any reactor operating period for Option A. Under Option B, preoperational Type A tests must be performed "after the containment has been completed and is ready for operation" (App. J, Option B, Section III.A.) and preoperational Type B and Type C tests must be performed "prior to initial criticality" (App. J, Option B, Section III.B.). Since Appendix J preoperational testing is likely to occur before fuel load, the NRC believes that it is appropriate to apply paragraph (o) from the time the COL is issued.

With regard to paragraphs (p) and (q), these provisions address maintenance of the security plans and the emergency plans, both of which are approved upon issuance of the COL.

Therefore, the NRC believes it is necessary to apply these provisions from the time the COL is issued. With regard to paragraph (q), the NRC has revised the first sentence in the final rule to indicate that the COL holder is not required follow and maintain in effect the emergency plans until after the Commission makes the finding under § 52.103(g).

In addition, the NRC believes that there are additional provisions, not mentioned by the commenters, that should not be applicable during construction, namely, paragraphs (n), (x), and (y). The exclusion of paragraph (n) during construction is consistent with the changes the NRC is making to § 50.45 regarding alterations to the facility. The exclusion of paragraphs (x) and (y) address situations where the licensee must take emergency action that departs from a license condition or technical specification when the action is needed to protect the public health and safety. Such a situation requiring the protection of public health and safety would not arise prior to fuel load.

In addition, the NRC believes paragraphs (r) and (u) do not apply at all to COLs and has revised § 50.54 to so state. Paragraph (r) only applies to research and test reactor facilities and paragraph (u) was only applicable for 60 days after the amendment to § 50.54 that added paragraph (u).

Comment 007-57: The commenters found that for COLs that reference a design certification, § 50.54(h) as currently worded would be inconsistent the backfit protections of § 52.63.

NRC Response: The NRC does not agree that § 50.54(h) is inconsistent with the backfit provisions of § 52.63. Section 50.54(h) states that the license shall be subject to the provisions of the Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. This provision further states that the terms and conditions of the license shall be subject to amendment revision, or modification by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms of the Act. The provision implements Section 183.d of the AEA, and makes it clear that because there is change to the AEA, or the Commission adopts a valid regulation after the issuance of a license, or issues an order to a licensee, the licensee should not assume that the new statutory provision or regulatory requirement does not apply to it, or that it may ignore the order, solely on the basis that these changes occurred after issuance of a license.

With respect to changes to the AEA, the new statutory requirement always control, and a licensee may not avoid compliance with a change to the AEA on the basis that the change was adopted by Congress after issuance of the license. With respect to new or changed regulations, the applicability of the regulation is controlled by the words of the regulation itself, or if there are no such words in the regulation, than it is applicable to all licensees absent more specific regulatory provisions. The finality provisions in Part 52, including Section 52.63, are an example of such specific regulatory provisions. Finally, with respect to orders, the Commission has power to issue an order, but only consistent with its regulations, unless it has a valid basis for "excepting" itself from its own regulations. In summary, Section 50.54(h) is not inconsistent with Section 52.63.

Comment 007-57: The commenters stated that current paragraph 50.54(u) imposes requirements on each nuclear power reactor licensee to submit to the NRC plans for coping with emergencies. The NRC should consider deleting this paragraph, as it is out of date and no

longer applicable to either operating reactors or new reactor applicants.

NRC Response: The NRC agrees that this paragraph is out of date and no longer applicable but deleting it is outside of the scope of this rulemaking, which is only meant to address issues related to Part 52. The NRC is not attempting to “clean up” Part 50 as part of this Part 52 rulemaking.

Comment 007-81: Several commenters stated that they considered changes in the NOPR in § 50.54(i-1), clarifying that operator requalification programs must be in effect within three months after the § 52.103(g) finding, to be beneficial. The commenters also stated that they considered changes in the NOPR in § 50.54(gg), regarding operation at up to 5 percent power notwithstanding Federal Emergency Management Agency identified deficiencies, provided the Commission makes a reasonable assurance finding, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.4.8 50.55(a) Codes and Standards

Comment 007-51: The commenters stated that the proposed change to § 50.55a(f)(3)(iii)(A) would constitute an inappropriate backfit. The design certifications issued prior to November 22, 1999, were required to utilize the applicable editions of the American Society of Mechanical Engineers (ASME) Code that were in effect and approved by the NRC at the time. Under the provisions in 10 CFR 52.63(a)(1) and § VIII.B.1 of the design certification rules, the NRC is not allowed to change those design certifications, except to assure adequate protection or to bring the designs into compliance with the Commission’s regulations “at the time the certification was issued.” The Commission has not made such a finding, and therefore the backfit contained in the proposed rule is inappropriate and in noncompliance with the Commission’s own regulations.

The commenters also stated that § 50.55a(g)(3) currently requires that the pre-service inspection of components be performed to the construction code to which the component was fabricated. When plants are under construction, the various components are fabricated to a number of editions and addenda to the construction code. It would be a tremendous burden to the industry to perform a pre-service inspection on multiple components to a number of different editions and addenda. It would be practical to choose one construction code edition and addenda as a code of record for the pre-service inspection. The commenters recommended that § 50.55a(g)(3) be revised.

NRC Response: The NRC disagrees with these comments. The proposed rule simply clarified the applicability of 10 CFR 50.55a. Clarifications of applicability and any periodic updates of § 50.55a do not constitute automatic backfits of existing design certification rules (DCRs). As stated in the comment, the applicable ASME Code editions and addenda are specified in the DCRs and any changes to these commitments would be controlled by § 52.63(a)(1).

Comment 007-82: Several commenters stated that the industry considers the changes in the NOPR in § 55.109, § 50.55a, regarding clarification of when the requirements would be applicable to operation under a combined license and that applicable ASME Code editions will

be those in effect 12 months prior to fuel loading, to be beneficial. The commenters recommended that the final rule amending Part 50 should include these changes.

NRC Response: No response necessary.

5.4.9 50.59-50.69 Issuance, Limitations, and Conditions of Licenses and Construction Permits

Comment 007-35: The commenters argued that the Supplementary Information for the proposed rule does not explain or justify requiring a COL holder to implement the maintenance rule prior to fuel load. Further, the requirement in proposed § 50.65(c) to implement the maintenance rule 30 days before fuel load is inconsistent with the requirement in paragraph 50.65(a) that the maintenance rule applies after the NRC has made its 52.103(g) finding.

The commenters noted that in no case has program implementation been required 30 days (or another arbitrary period) prior to a project/licensing milestone, and that doing so for the maintenance rule would provide no discernable regulatory or operational value. Indeed, the NRC provides no justification for it.

The commenters recommended that NRC should not require implementation of the maintenance rule prior to fuel load when not all systems will have been placed in service. Moreover, most of the requirements in the maintenance rule, such as the monitoring and assessment activities in § 50.65(a), are predicated upon an operating plant. That said, it should be emphasized that, regardless of any NRC requirement, the licensee will have implemented its maintenance programs, as well as its quality assurance and configuration control programs, long before fuel load to maintain and control the configuration of SSCs as they are turned over to operations and placed into service.

NRC Response: The NRC agrees with this comment and has deleted the proposed revision to § 50.65(c). The NRC expects that licensees will have the maintenance program operational by the time that initial fuel loading has been authorized.

Comment 007-58: Regarding the proposed changes to 10 CFR 50.61 that would make this section applicable to a COL holder, among other requirements, this section requires a calculation of reference temperature pressurized thermal shock (RT_{PTS}). The commenters noted that the calculation of RT_{PTS} depends upon material properties of the reactor vessel. At the time of issuance of a COL, it is possible that the reactor vessel may not have yet been manufactured, and therefore its material properties may not be sufficiently known for the purposes of calculating RT_{PTS} . Therefore, the proposed rule should be modified to indicate that § 50.61 applies to a COL at the time the NRC makes its 52.103(g) finding.

NRC Response: The NRC does not agree with the commenter's recommendation. The reactor vessel may be purchased prior to issuance of the COL and the calculation of RT_{PTS} can be resolved during the COL review. For those licensees that purchase their reactor vessel after receipt of the COL, the verification of the reference temperature can be performed with an ITAAC. Therefore, the rule language was not changed.

Comment 007-64: Regarding the proposed changes to 10 CFR 50.59(b) and 52.98 that would

make the change process in § 50.59 applicable to holders of COLs, the commenter noted that under the existing provisions in § 50.59(c), certain types of changes require a license amendment. The commenter stated that § 50.59 should be applicable to COL holders as soon as the COL is issued. However, during the period of construction, the commenter stated that a clarification of the 50.59 process is warranted. The commenter cited existing § 50.59 guidance in NEI 96-07, Guidelines for 10 CFR 50.59 Implementation, which has been accepted by the NRC in Regulatory Guide 1.187 § 4.5.

The commenter noted that many times during construction, minor changes are needed or minor nonconformances arise that are acceptable as-is from a safety perspective. For those changes needing NRC approval under § 50.59, it should be acceptable to make the change at the risk of the licensee, document and control the change as an issue needing further approval, and then confirm the acceptability of the change after the fact to allow construction activities to proceed pending NRC approval of a license amendment. This should be permitted for any changes to structures, systems, or components that have not yet been placed in service. Such a process would be consistent with the existing guidance in NEI 96-07 that is quoted above.

NRC Response: The NRC generally agrees that it would be appropriate to apply the guidance outlined in NEI 96-07 and accepted in NRC Regulatory Guide 1.187 regarding when an activity is “implemented” to COLs during construction. The NRC does not believe, however, that any change to the proposed rule language or statements of consideration is necessary.

Comment 007-68: The commenters argued that the language of 10 CFR 50.69, which allows design certification applicants the option of using the categorization methodologies, is vague and confusing. It has been interpreted as precluding design certification applicants from using the alternative categorization methodologies. Thus, for new plants licensed under Part 52, each combined license applicant that chooses to adopt § 50.69 must perform an extensive analyses and make a submittal to the NRC for an exemption from the structure, system, and component categorization process used in certifying the design. The commenters indicated that in the 1999 staff requirements memorandum on SECY-98-300, Options for Risk-informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities, the Commission approved the NRC staff proposal to risk-inform the scope of systems, structures, and components covered by those sections of Part 50 requiring special treatment (e.g., Quality Assurance, Environmental Qualification, Technical Specifications, § 50.59, ASME code, § 50.72, and § 50.73). The commenters argued amending the language of § 50.69 to clarify that design certifications have the option of using § 50.69 would improve regulatory efficiency and reduce the regulatory burden on combined license applicants and on the NRC staff by allowing the design certification applicant to submit the categorization evaluations just once to the NRC instead of numerous times.

Comment 005-16: The commenter stated that in 10 CFR § 50.69(b)(1), the applicability of the risk-informed categorization and treatment process specifically omits applicants for design certification. Although the NRC explained its rationale for this omission in the *Federal Register* notice for the 10 CFR 50.69 rulemaking (see 69 FR 68035), the commenter did not find those arguments persuasive, particularly in view of the fact that the risk-informed categorization and treatment process is permitted in applications for standard design approval, for which the technical requirements are essentially the same as for design certification.

One of the reasons provided for omitting design certification applicants from applying the 10 CFR 50.69 process was that “the industry has not expressed any interest in submitting a design certification using the principles of § 50.69.” However, when the proposed rule for § 50.69 was published, there was no provision for including design certification applicants, and the NRC did not request comments as to whether such a provision should be included. Thus, the industry was never given an adequate chance to express its interest in such a provision. Consequently, NEI now expresses the industry’s interest in including design certification applicants in the “applicability and scope” section of 10 CFR 50.69.

The commenter recommended that 10 CFR 50.69(b)(1) be amended, and noted that the applicability of § 50.69 requirements to design certification applicants would be defined by the current 10 CFR 50.69(b)(4).

NRC Response: The NRC did not propose any revisions to § 50.69 in this rulemaking and does not agree that § 50.69 should be applicable to design certification applicants. It is important to remember that § 50.69 is a voluntary regulation and COL applicant's who choose to adopt that requirement must first classify their equipment into safety-related and non-safety related categories. Then they can reclassify into the four categories identified in § 50.69. If design certification rules were issued under § 50.69, the COL applicants referencing that certified design would have to adopt the four category approach and lose the voluntary option of § 50.69. Whereas, if design certification applicants do not use § 50.69, then they would all do the mandatory part of the component categorization (safety-related and non-safety related) and subsequently the referencing COLs could voluntarily choose to convert to the four categories of equipment. Furthermore, it is not apparent that sufficient information would be available at the design certification stage to meet the requirements of § 50.69.

5.4.10 50.70-50.75 Inspections, Records, Reports, Notifications

Comment 007-36: The commenters noted that the combined license holder is required to submit a decommissioning funding report in its application, explaining how it will fund decommissioning. The annual update during the construction period would serve no purpose and is unnecessary and unduly burdensome. In addition, such a reporting requirement is not imposed on construction permit holders. The licensee should be allowed to adjust the funding certification at the time construction is complete and the plant is ready to begin operation.

The annual update under § 50.75(e)(3) should not be required prior to the date that the NRC makes the § 52.103(g) finding. Once the NRC has issued its § 52.103(g) finding, the licensee will be subject to decommissioning funding requirements, and must submit periodic reports as provided in § 50.75(f)(1). This approach appears to be consistent with the other requirements in 10 CFR 50.75 for establishing decommissioning funding, and also would accomplish the intent of the regulatory scheme established to ensure adequate decommissioning funding upon the end of the operational life of the plant, as discussed in the NOPR.

NRC Response: The commenter is correct that a decommissioning reporting requirement is not imposed on construction permit holders. However, under the current rule, an operating license applicant must submit to the NRC a copy of the financial instrument obtained as part of the certification contained in the applicant's required decommissioning report. Also, the amount of decommissioning funding assurance to be provided must be adjusted annually by an

operating license applicant. The result is that the NRC will have adequate time to evaluate the financial instrument, which must cover adjusted funding amounts. The Commission believes that for combined licenses, a certain amount of time is also necessary prior to the time the plant is ready to begin operation to allow the NRC to confirm that any significant escalation in decommissioning costs is accounted for by the licensee, and to evaluate the financial instrument the applicant is planning to obtain to satisfy decommissioning funding assurance requirements, particularly non-routine financial instruments that could be used with unconventional funding assurance mechanisms. Therefore, the Commission has concluded that updated annual certifications including a copy of the financial instrument to be used are necessary beginning two years prior to the scheduled date for fuel load. Accordingly, the Commission has decided that the final amendment to 10 CFR 50.75 will eliminate the need for an annual update to the required decommissioning report during the entire time prior to the making of the finding under 10 CFR 52.103(g), and instead require only updates two years and one year before the scheduled date for fuel load. The final amendment will also clarify that a copy of the financial instrument to be obtained, i.e., unexecuted, will be required to be part of the certification contained in the updates of the decommissioning reports to be submitted. The final rule retains the requirement in the proposed rule that an updated decommissioning report, containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification and containing as part of the certification a copy of the financial instrument obtained, must be submitted no later than 30 days after the Commission publishes notice in the Federal Register under 10 CFR 52.103(a).

Comment 007-59: The commenters noted that given the other changes in the proposed rule, § 50.72 could now be construed as applying to a COL upon its issuance. Therefore, the proposed rule should be modified to indicate that § 50.72 applies to a COL only after the NRC makes its 52.103(g) finding.

NRC Response: The NRC agrees with the commenter and has include changes to § 50.72 in the final rule to indicate that it is applicable to COLs only after the NRC makes the finding under § 52.103(g).

5.4.11 50.78 US/IAEA Safeguards Agreement

No comments received.

5.4.12 50.80-50.82 Transfers of Licenses - Creditor's Rights - Surrender of Licenses

New Requirements Related to Transfer of an ESP

Comment 007-22: Several commenters noted that proposed 10 CFR 52.28 would specify that an "application to transfer an ESP will be processed under 10 CFR 50.80." Section 50.80(a) would be revised to include permits issued under Part 52 within the scope of the regulations for transfer of licenses. The commenters agree that an ESP should be subject to transfer, and that NRC regulations should include criteria governing the transfer of ESPs. However, the commenters do not believe that all of the requirements in § 50.80 are relevant to such transfers (e.g., requirements on financial qualifications, requirements for technical qualifications). The commenters suggested that the final rule should reflect that such a transfer would be subject to the "applicable" requirements in 10 CFR 50.80. The commenters also noted that, based upon

the December 27, 2005, NRC staff response to the Commission's SRM on the draft proposed rule, the commenters understood that the NRC agrees with the above comment.

NRC Response: The NRC agrees that not all of the requirements in § 50.80 are relevant to transfers of an ESP and has made changes to § 50.80 in the final rule to specify which criteria are applicable to transfer of an ESP. Specifically, in the final rule, paragraph 50.80(b)(1)(ii) requires an application for transfer of an ESP to include as much of the information described in §§ 52.16 and 52.17 with respect to the identity and technical qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. This change removes the requirement for the applicant for transfer of an ESP to address financial qualifications since this is not required of an initial ESP applicant. In addition, this change removes, for an ESP transfer, the statement that the Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applications' qualifications to protect against such hazards since an ESP does not authorize the holder to possess radioactive material.

5.4.13 50.90-50.92 Amendment of License or Construction Permit at Request of Holder

No comments received.

5.4.14 50.100-50.103 Revocation, Suspension, Modification, Amendment of Licenses and Construction Permits, Emergency Operations by the Commission

No comments received.

5.4.15 50.109 Backfitting

Comment 007-83: Several commenters stated that the industry considers the changes in the NOPR in § 50.109, regarding applicability of the Backfit Rule, to be beneficial. The commenters recommended that the final rule amending Part 50 should include these changes.

NRC Response: No response necessary.

5.4.16 50.110-50.111 Enforcement

No comments received.

5.4.17 50.120 Training and Qualification of Nuclear Power Plant Personnel

No comments received.

5.4.18 Appendix A - General Design Criteria for Nuclear Power Plants

No comments received.

5.4.19 Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

5.4.20 Appendix C - A Guide for Financial Data and Related Information Required to Establish Financial Qualifications for Facility Construction Permits

No comments received.

5.4.21 Appendix E - Emergency Planning and Preparedness for Production and Utilization Facilities

Comment 007-84: Several commenters stated that they considered the changes in the NOPR in Appendix E to Part 50 Emergency Planning and Preparedness for Production and Utilization Facilities, § IV.f.2.a.ii, regarding conduct of the full participation exercise within two years of fuel load, to be beneficial. Several commenters also regarded the changes to Appendix E to Part 50 Emergency Planning and Preparedness for Production and Utilization Facilities, § IV.f.2.a.iii, regarding coordination of the EP exercise for the new plant with that for the operating unit(s), also to be beneficial. The commenters recommended that the final rule amending Part 50 should include those changes.

NRC Response: No response necessary

5.4.22 Appendix F - Policy Relating to the Siting of Fuel Reprocessing Plants and Related Waste Management Facilities

No comments received.

5.4.23 Appendix G - Fracture Toughness Requirements

No comments received.

5.4.24 Appendix H - Reactor Vessel Material Surveillance Program Requirements

No comments received.

5.4.25 Appendix I - Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet ALARA for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents

No comments received.

5.4.26 Appendix J - Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors

No comments received.

5.4.27 Appendix K - ECCS Evaluation Models

No comments received.

5.4.28 Appendix L - Information Requested by the Attorney General for Antitrust Review of Facility Construction Permits and Initial Operating Licenses

No comments received.

5.4.29 Appendix R - Fire Protection Program for Nuclear Power Facilities Operating Prior to Jan. 1, 1979

No comments received.

5.4.30 Appendix S - Earthquake Engineering Criteria for Nuclear Power Plants

Comment 005-18: The commenter stated that the NRC's approach to revising existing parts of 10 CFR is not internally consistent. For example, the term "design certification" is used in the revised Part 50 (see, e.g., new 10 CFR 50.43), but is not included in the new definitions proposed for 10 CFR 50.2. However, a definition for "design certification" is included separately in the new 10 CFR Part 50, Appendix S. The commenter noted that the definition in new 10 CFR 52.1 is given for "standard design certification or design certification," which is not the same as the terminology in the aforementioned Appendix S.

NRC Response: The NRC disagrees with this comment and has determined that the definition of "design certification" in 10 CFR 52.1 and Appendix S to 10 CFR Part 50 are substantively equivalent. Also, the requirement in 10 CFR 50.43 refers to "design certification under part 52." Therefore, the reader would use the definition of design certification in 10 CFR 52.1.

Application Processing

5.5 Changes to 10 CFR Part 1

No comments received.

5.6 Changes to 10 CFR Part 2 – Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders

Comments 003-9, 003-10, 003-11, and 003-17: Several commenters asked why the model schedule in Appendix B to Part 2 allows the presiding officer an additional 55 days to issue a hearing schedule. The commenters suggested that the initial hearing schedule could be established at the same time that the presiding officer issues a decision ruling on intervention and admission of contentions, i.e., within 140 days after publication of the hearing notice. Several commenters believed that the time interval in the model schedule for the beginning of licensing hearings should be shortened considerably. Under Part 2, Subpart L, hearings on COL applications should begin 175 days after issuance of the safety evaluation report (SER) and NEPA document (e.g., environmental impact statement or EIS). The commenters recommended that the hearings proceed based on the information contained in the draft SER and draft EIS, or alternatively, the hearings should begin more promptly than 175 days after issuance of the final SER and final EIS if no additional contentions on the final documents are admitted.

NRC Response: The 55 day-period provided in the Model Schedule for Appendix L hearings was established for several reasons. Section 2.332(a) requires the presiding officer to set a scheduling order only after consulting with the parties by conference, telephone, mail, or other suitable means. Furthermore, § 2.332(d) provides that, in establishing the schedule, the presiding officer considers the NRC staff's schedule for completion of the safety and environmental evaluations. That schedule may depend upon the contentions admitted, inasmuch as the NRC staff may choose to prioritize its evaluations and issue its evaluations in a phased approach to support timely hearings on those matters. See 69 FR 2208-2209. The Commission also notes that once the order admitting parties and contentions is issued, mandatory disclosures must be made automatically under § 2.336(a); the Commission believes that once parties have had a reasonable period of time to assess the disclosed information, the scheduling of the remainder of the hearing will be better-informed. Certainly, the agency's general - if not always consistent - practice prior to adoption of the 2004 revisions to Part 2 was to establish a schedule for completion of the hearing (e.g., summary disposition, submission of pre-filed direct and rebuttal testimony, and cross-examination plans) only after completion of discovery, and some cases only after issuance of the primary NRC staff documents. Thus, the Commission believes that it is reasonable to provide some time for the NRC staff, as well as other parties, to prepare for a scheduling conference. After completion of the scheduling conference, the Commission believes that, depending upon the nature and complexity of the proceeding, the presiding officer will require some time to prepare the scheduling order. Finally, the Commission notes that the Milestones in Appendix B of Part 2 are intended to be general guidelines, and if circumstances permit or necessitate somewhat reduced time periods, the presiding officer has sufficient flexibility to do so, consistent with § 2.332(b), (c), and (d).

Comments 003-1, 003-6, and 013-2: Several commenters recommended that NRC modify the regulations to provide explicitly for the submittal of phased applications and standardized application sections. Specifically, they said that 10 CFR 2.101 should be revised to clarify to NRC that these approaches are acceptable, and this suggestion particularly applies to resolution of DAC and COL action items. They cited several key benefits. Phased submittals and corresponding phased NRC review of COL applications would facilitate completion of the review of potentially extensive portions of the license applications at an earlier date. This in turn would accelerate the overall license review schedule and would permit earlier commencement of hearings. They suggested that standardized license applications will take less time for review than in the past. The commenters suggested that this approach is likely to give NRC staff greater flexibility in allocating its resources, which should lead to more effective use of NRC resources overall. Additionally, it should enable the NRC to issue its formal approvals earlier than it would otherwise be able to do so, since the early submittals could be removed from the critical path.

The commenters illustrated their point with a hypothetical example in which a COL applicant might file those portions of its application that pertain to environmental and siting issues sooner than those portions that pertain to the plant design, to permit early resolution of those issues. They suggested that such early resolution might support the issuance of a limited work authorization under 10 CFR 50.10(e).

NRC Response: The final rule includes revisions to 10 CFR 2.101, and 10 CFR Part 2, subpart F, to clarify that the existing process for phased submission of applications addressing environmental and siting matters separate from safety matters.

The NRC declines to adopt a more general approach for phased applications. An efficient and effective review process requires that each “phase” of a submitted application be essentially complete and self contained. If the portion of the application submitted is not complete, the NRC’s review is likely to be time consuming and possibly incomplete, which would defeat the underlying purpose of the phased submission. The commenters did not address these concerns, nor did they propose criteria or guidelines for ensuring that the portions of applications which are submitted are complete and self contained. Given the difficulties of the phased submission of partial applications with no constraining requirements, and the additional flexibility provided in the final rule as compared with the proposed rule (e.g., extension of Appendix N in Part 52 to duplicate designs, revisions to § 2.101 and Part 2, subpart F as described above, and revisions to the LWA process in 10 CFR 50.12), the NRC believes that the final Part 52 rule provides a sufficiently broad array of administrative and procedural alternatives to potential applicants.

Comment 003-7: Several commenters believed that the establishment of model milestones or recommended schedules would reduce the time taken for the staff to complete licensing reviews and issue safety and environmental licensing documents. They suggested that the Commission should direct NRC staff to docket applications more quickly and complete key licensing documents (e.g., SER, EIS) by a certain deadline, or explain why it cannot do so. The commenters stated that these efforts will facilitate the earlier initiation and, therefore, completion of licensing hearings, because initiation of hearings is linked to the availability of the licensing documents.

Commenter 003 suggested three timeline requirements for the Commission’s consideration:

(1) Require NRC staff to docket an early site permit (ESP), design certification (DC) and COL application within 30 days after the application is filed with the NRC. (NRC regulations in 10 CFR 2.101(a)(2) treat this 30-day review period as a goal, not a requirement.)

(2) Require NRC staff to complete and issue the draft SER or SER with open items and the draft EIS within 12 months after docketing an ESP or “first of class” COL application. For subsequent standardized COL applications, the turnaround time for the draft licensing documents should be shorter. This period could be even shorter for a COL application that references a certified design or a reference COL application.

(3) Require NRC staff to complete and issue the final SER and the final EIS within four months after issuance of the draft SER and EIS. This period could be even shorter for a COL application that references a DC and/or ESP.

NRC Response: The Commission disagrees with the commenter’s general proposal that the Commission establish Model Milestones or (generic) recommended schedules for the Staff to complete its licensing responsibilities. The Commission considered this in the recent Part 2 rulemaking (69 FR 2182; January 14, 2004) and rejected that approach, and the commenter presented no reason for revisiting the Commission’s earlier conclusion. The Commission believes that these are matters of internal agency management, and are not appropriate subjects for rulemaking. The Commission is considering other approaches for addressing this matter, either through issuance of generic guidance to the Executive Director for operations or through case-specific Commission action. Accordingly, the Commission declines to adopt the

commenter's proposal, and no change to any part of the final Part 52 rulemaking has been made as the result of the comment.

The Commission notes that the commenter's proposed time periods for issuance of draft SER and EIS for either an early site permit or a "first of class" combined license, and for issuance of a final SER and final EIS are likely unachievable. For example, the commenter suggests that the final EIS be issued within 4 months (120 days) after issuance of the draft EIS. Under § 51.73, a minimum 45-day comment period must be provided. This provides 75 days for the NRC staff to assess comments, revise the EIS, provide the EIS to the US Environmental Protection Agency for review, and receive EPA's notification of their approval. It may be possible to achieve the schedule in a combined license proceeding where the application references either a standard design certification rule or an early site permit. However, the Commission has no experience with the time needed for review of a combined license, and regards the uncertainties as sufficiently large that it would be imprudent to establish model milestones by rulemaking at this time.

Comments 003-12: Several commenters suggested that the NRC should amend proposed 10 CFR 2.340(e) to clarify that a licensing board decision authorizing issuance of an ESP is immediately effective. This change could save two months or more on the schedule for pre-construction activities for a facility, without affecting the substance of the NRC's review. A licensing board decision authorizing a COL is already immediately effective under § 2.340(h), and ESP decisions should not be treated more restrictively than COL decisions.

NRC Response: The Commission is making changes to §§ 2.340 which render this comment moot.

Comments 003-11, 003-17, and 013-7: Several commenters believed that the schedule for an initial decision on a COL application should be reduced. These commenters the NRC should shorten many of the time intervals specified under Part 2, as applied to 10 CFR 52.103 hearing activities, to facilitate the earlier initiation and completion of the hearings. The model schedule for hearings on COL applications conducted under Part 2, Subpart L, states that the presiding officer should issue an initial decision within 90 days after the end of the hearing and the close of the record, and the commenters thought the time should be reduced to 60 days or less after the close of the record.

NRC Response: The Commission shares with the commenters the goals of regulatory effectiveness and efficiency in licensing and the conduct of hearings. The Commission has monitored - even before the recent adoption of the model milestones in Part 2 (70 FR 20457; April 20, 2005) - the Atomic Safety and Licensing Board adherence to the Commission's direction in its current policies on adjudication. See *Policy Statement on the Conduct of Adjudications*, CLI-98-12, 48 NRC 18 (July 28, 1998), 63 FR 41872 (August 5, 1998); *Statement of Policy on Conduct of Licensing Proceedings*, CLI-81-8, 13 NRC 452 (May 20, 1981), 46 FR 28533 (May 27, 1981).

However, the Commission does not believe that it is appropriate, given the lack of any Commission experience in the conduct of proceedings for either the issuance of combined licenses or the § 52.103 hearings, to make any rulemaking changes in Part 2 to explicitly address the conduct of combined license proceedings. In particular, the Commission does not

believe that it is appropriate, in light of the commenter's failure to specify any particular problem with the Atomic Safety and Licensing Board's implementation of the set of model milestones in any of the current early site permit proceedings (or indeed, in any other proceeding), to consider establishing by rule a set of model milestones, binding schedules, or accelerated time periods for the filing of specific pleadings or the issuance of presiding officer orders and decisions, which would be specific to early site permits, combined license issuances, or to § 52.103 hearings.

The Commission is considering other approaches for addressing this matter, either through issuance of generic guidance to the Atomic Safety and Licensing Board Panel, or through case-specific Commission action. The Commission also intends to continue its active oversight of the Atomic Safety and Licensing Board. The Commission believes that these actions will be sufficient in the near term to ensure regulatory effectiveness and efficiency in the hearing process for the expected early site permit and combined license applications expected in the near term. Accordingly, the Commission declines to adopt any of these commenters' proposal at this time, and no change to any part of the final rule has been made as the result of the comment. The Commission may adopt one or more of the suggested changes in the future, if the Commission determines they are warranted based upon new information or changed circumstances.

Comment 005-22: One commenter disagreed with the requirement for a mandatory hearing for manufacturing licenses. The commenter suggested that the NRC should either leave such hearings to the Commission's discretion or provide the capability for a stakeholder to request a hearing.

NRC Response: See response to Commission Question 15 in Section 4.15 of this document.

Comment 007-15: Several commenters recommended that proposed § 2.105(b)(3)(iv), which states that the notice of intended operation under § 52.103(a) may identify "conditions, limitations or restrictions to be placed on the license in connection with the finding under § 52.103(g)," should be deleted from the final rule. The commenters believed that there is no basis for the NRC to impose license conditions as part of the § 52.103(g) finding. They pointed out that the policy underlying the licensing reforms of the Energy Policy Act of 1992 was that all licensing requirements would be known at the time the COL was issued.

NRC Response: The Commissioner disagrees with the commenters. This provision is intended to permit the NRC to allow interim operation if there is either: (i) a matter of ITAAC compliance that may be resolved during a period of fuel loading and/or interim operation under appropriate conditions, limitations or restrictions; or (ii) the NRC determines that there is a significant matter of non-compliance with the Commission's regulations that would otherwise form the basis for an order suspending operation in the absence of such conditions, limitations or restrictions. Thus, if an issue arises that can be corrected by the combined license holder during a period of interim operation under appropriate conditions, limitations or restrictions, the NRC can permit interim operation without undue delay. Interim operation is specifically provided for in Section 189.a(1)(B)(iii) of the AEA, which was adopted as Section 2808 of the Energy Policy Act of 1992. The commenters presented no legal argument supporting its position that inclusion of conditions, limitations or restrictions as part of a § 52.103 finding to permit interim operation is prohibited by the Energy Policy Act of 1992.

Comment 013-7: A commenter recommended that NRC should affirmatively control the COL hearing process including use of Commission-imposed and enforced firm schedules for completion of hearings and timely issuance of decisions. The commenter commends the Commission's effectiveness in controlling the Louisiana Enrichment Services uranium enrichment facility licensing by the adoption of detailed adjudicatory milestones in that case (CLI-04-03, dated January 30, 2004).

NRC Response: The Commission disagrees with the commenter's suggestion, to the extent that it calls for adoption of firm schedules by rulemaking. The Commission has already adopted Model Schedules, and requirements in §§ 2.332 and 2.334 for presiding officers to develop a specific schedule in each proceeding based upon the applicable Model Schedule, and to inform the Commission when there will be a delay of more than 45 days in meeting any of the dates for the major activities in the schedule for the proceeding. Furthermore, the Commission intends to maintain its current close oversight of hearings conducted by the Atomic Safety and Licensing Board. The Commission considered the arguments in favor and against the adoption of mandatory schedules when it rejected mandatory schedules and adopted the Model Milestones, see 70 FR 20457 (April 20, 2005). The commenter presented no reason why the Commission should revisit its decision, and perhaps most importantly did not identify any example where the Atomic Safety and Licensing Board has failed to adhere to the Model Milestones or the requirements of §§ 2.332 and 2.334. In the absence of any cogent reason in favor of abandoning the approach we adopted less than 2 years ago, the Commission rejects the commenter's suggestion.

Comment 007-27: Several commenters recommended that the proposed provision in § 2.104(d)(1)(v) [cited by commenter as § 2.104(d)(v)], which would impose requirements for an ESP applicant to demonstrate technical qualifications, should be deleted. The commenters objected to these additional requirements on ESP holders because they are not authorized to conduct any safety-related construction activities.

NRC Response: The Commission does not agree with the commenter that a technical qualifications determination of an early site permit applicant is unnecessary because the holder is not authorized to perform "safety-related" construction. The early site permit applicant is responsible for other activities, having a public health and security or common defense and security, for which a technical qualifications finding is necessary. For example, the early site permit holder is required to provide a safety assessment of the site on which the facility may be located, see § 52.17(a)(1)(ix), a description of the quality assurance program to be applied to site-related activities for design, fabrication, construction, and testing of structures, systems and components that may be constructed, see § 52.17(a)(1)(ix), and at minimum provide physical characteristics of the site that could pose a significant impediment to the development of an emergency plant, and measures that would mitigate or eliminate such significant impediments, see § 52.17(b)(1). Such activities, if performed in a technically-inadequate manner, may have a significant impact on public health and safety or common defense and security. Accordingly, the Commission concludes that Section 182.a of the AEA requires the Commission to find that the early site permit applicant possesses the necessary technical qualifications for conducting those activities, and rejects the commenter's implicit suggestion that the technical qualifications requirement for early site permit applicants be removed from the final rule.

Comment 007-50: Several commenters objected to the proposed changes to § 2.104 that identify the contents of notices of hearings for construction permit, ESP, and COL proceedings, including findings to be made by the presiding officer in those proceedings. The changes do not fully incorporate the NRC's conclusions in its Memorandum and Order CLI-05-17 (July 28, 2005) as to the findings that must be made by the Atomic Safety and Licensing Board for a mandatory hearing. Additionally, the proposed rule does not explain why additional findings should be added to the notice of hearing.

NRC Response: The Commission agrees with the commenter that the proposed changes to § 2.104 does not alter the "ambiguous" language in that was the subject of the Commission's order in Exelon Generation Co., LLC (Early Site Permit for Clinton ESP Site) , et al., CLI-05-17, 62 NRC 5 (2005). The Commission's view is that its decision is sufficiently clear that changes to the rule language which were the subject of the Commission's order, would re-introduce some uncertainty into the regulations. Hence, the Commission did not revise the language to "conform" to the Commission's decision on the distinction between contested versus uncontested "issues," the Commission's admonition against de novo review of uncontested issues by the presiding officer, and the prohibition against an intervenor's prohibition on uncontested matters. On these matters, CLI-05-17 provides clear direction. The Commission believes that a generic change should be accomplished in § 2.104 for all proceedings - not just proceedings involving Part 52 permits and licenses, and such rulemaking is outside the scope of the Part 52 rulemaking. Accordingly, the Commission declines to adopt the commenter's proposed changes to § 2.104.

In retrospect, the Commission agrees with the commenter that the SOC for the proposed rule did not provide rationales for adopting additional findings with respect to the various Part 52 permits and licenses. To explain, the Commission's intent was to ensure that the required findings, as set forth in §§ 2.104, 51.105, 51.105a and 51.107, are consistent with the necessary findings which must be made under relevant provisions of the AEA. For example, the findings on early site permits (which may include ITAAC) and combined licenses include a finding with respect to ITAAC, are required by or are consistent with Section 185.b.; and the findings on "technical qualifications" are required by, or are consistent with § 182.a of the AEA. In addition, the Commission added language that reflects the findings set forth in §§ 52.24 and 52.97. For example, the proposed § 2.104(d)(1)(ii) finding specified for early site permits on necessary notifications is drawn from current § 52.24 (which was proposed to be retained in proposed § 52.24(a)(2). The Commission does not regard the incorporation of the findings in §§ 52.24 and 52.97, which have already been approved by the Commission in the 1989 Part 52 rulemaking, as either expanding or contracting in any substantive manner the issues for which findings must be made under § 2.104, or otherwise introducing a new legal problem or ambiguity. The commenters do not appear to have identified any specific legal problem with the proposed findings; rather, they were simply seeking Commission explanation for the changes. Accordingly, the Commission has not made any changes to the final rule as a result of these comments. However, if any commenter, upon reflection, believes that there is a new legal problem introduced by the changes to § 2.104, they may submit a petition for rulemaking, requesting the Commission to correct the matter.

Comment 007-43: The commenters recommend that the NRC retain Appendix Q in Part 52, as well as in Part 50. The commenters stated that while no applicant has yet expressed an intent to use the early site review process in Appendix Q or the process in Subpart F to Part 2

for partial decisions on site suitability issues, these processes may provide important flexibility for early and efficient consideration of site suitability issues for COL applicants. There is no reason to eliminate this flexibility, and no harm is caused by allowing Part 52 applicants to utilize these provisions.

Both of these regulations allow critical path site issues to be reviewed by NRC in advance of the submission of a COLA, in cases where the applicant's schedule or other considerations does not allow it to complete the ESP process in advance of the COLA. Further, utilization of Appendix Q or Subpart F in the context of a COLA could allow the NRC staff to more efficiently utilize its resources to focus early review of site issues only on those issues sought by the applicant, rather than the full scope of issues required by an application for an ESP.

In the August 2005 draft of the proposed rule, changes were indicated in 10 CFR Part 2, Subpart F that would have allowed the Subpart to be used in the Part 52 COL process. This change is not part of the proposed rule noticed in the *Federal Register*. Thus, one could (erroneously) conclude that Part 2, Subpart F, is only applicable to the Part 50 construction permit process. The commenters suggest that the August 2005 draft revisions to Subpart F be incorporated into the final Part 52 rule to clarify its continuing availability to Part 52 applicants.

NRC Response: The final rule includes changes to § 2.101 and 10 CFR Part 2, subpart F, which clarify its applicability to Part 52 combined license applicants.

Comments 007-62 and 007-73: Several commenters noted that Section 625 of the Energy Policy Act of 2005 eliminated the antitrust review of an applicant for a license to construct or operate a utilization facility or production facility under Section 103 or 104.b of the Atomic Energy Act of 1954, as amended. Thus, § 2.104(l) of the proposed rule should be deleted, and provisions related to antitrust reviews in §§ 50.33a, 50.41(c), 50.42(b), and 50.54(g) of the existing rules should be deleted.

NRC Response: The Commission agrees with the commenters that § 2.104(l) in the proposed rule (which represented a redesignation of former § 2.104(d)) need not be included in the final rule. Section 625 of the Energy Policy Act of 2005 (2005 EPA) removed the need for antitrust reviews for production and utilization facilities licensed under Section 103 or 104.b. of the AEA whose applications are filed after the date of enactment of the 2005 EPA. For the same reason, the Commission also agrees with one commenter that §§ 50.41(c) and 50.42(b), which address antitrust review of applications, should be removed from Part 50. Accordingly, the Commission has not included § 2.104(l), and has removed §§ 50.41(c) and 50.42(b). The latter two changes may be made in the final rule without notice and opportunity for public comment, inasmuch as these changes are non-discretionary rulemakings intended to comply with the 2005 EPA. Accordingly, in accordance with the APA, 5 U.S.C. 553(b)(3)(B), the Commission finds that notice and public comment on these changes are unnecessary.

However, the Commission disagrees with the commenters' suggestion that § 50.54(g) should be deleted to be consistent with Section 625 of the 2005 EPA. Section 50.54(g) continues to be applicable for existing licensed nuclear power plants with antitrust conditions included in their operating licenses. Accordingly, it is not appropriate to remove this section from the Commission's regulations as part of the Part 52 rulemaking.

Comment 007-80: Several commenters supported the proposed changes to §§ 2.1, 2.100, 2.105, 2.106, 2.109, 2.390, and 2.800.

NRC Response: No response necessary.

5.7 Changes to 10 CFR Part 10

No comments received.

5.8 Changes to 10 CFR Part 19 – Notices, Instructions and Reports to Workers: Inspection and Investigations

Comment 007-17: Several commenters objected to the provisions in proposed § 52.5(a) and parallel provisions in Part 19 that apply to employee protection requirements to design certification applicants and design approval applicants. The commenters recommended that changes suggested for Part 52 also should be made in Part 19.

NRC Response: The NRC disagrees with the comment that application of employee protection requirements to design certification applicants and applicants for design approval “is inappropriate and unauthorized under Section 211 of the Energy Reorganization Act (the Act). As stated in the Supplementary Information section of the proposed rule, the NRC believes that its regulatory authority under Section 211 and Section 401 of the 1974 ERA is much broader than the current scope of Part 19. The anti-discrimination proscriptions in Section 211 of the ERA apply to any “employer,” which the NRC regards as including non-licensee entities otherwise regulated by the NRC, such as applicants for and holders of standard design approvals, and applicants for standard design certifications. The Commission believes that the use of the term, “includes,” in paragraph (a)(2) of Section 211 of the 1974 ERA was not intended to be an exclusive list of the persons and entities subject to the anti-discrimination provisions in that section. The House Report on H.R. 776, which was adopted by Congress as the Energy Policy Act of 1992, states:

[Title V] also broadens the coverage of existing whistle blower protection provisions to include...any other employer engaged in any activity under the Energy Reorganization Act of the Atomic Energy Act of 1954.

H.Rep. No. 102-474, Part 8, 102d Congress, 2d Sess., at 78-79 (1992) (emphasis added). There was no discussion of the statutory language in the conference report. H.R. Conf. Rep. No.102-1018, 102d Cong., 2d Sess. (1992). Commenters did not provide any reason why the Commission’s interpretation of “includes” is incorrect. The Commission’s interpretation is reasonable because design certifications and design approvals help to form the basis for NRC safety determinations with respect to licensing of nuclear power plants referencing the design certifications or design approvals. Accordingly, in the absence of any showing that the Commission’s interpretation is incorrect or otherwise unreasonable, the NRC rejects the comments and has made no changes in the final rule. The NRC also does not agree with the commenters’ suggestion that § 52.5(a) should apply only during those periods in which the applicant for design certification or design approval is actively engaged in regulated activities. The NRC believes that employees should be able to raise safety concerns related to a design

approval or design certification at any time without fear of retaliation.

Comment 007-41: Several commenters recommended deletion of § 19.11(b)(2), which would require various applicants to post “The operating procedures applicable to the activities regulated by the NRC which are being conducted by the applicant or holder.” The commenters pointed out that applicants and holders may have volumes of operating procedures and posting them all would be impractical.

NRC Response: The NRC does not agree that proposed § 19.11(b)(2) should be deleted. Proposed § 19.11(d) states that, if posting of a document is not practicable, the licensee or regulated entity may post a notice which describes the document and states where it may be examined.

5.9 Changes to 10 CFR Part 20

No comments received.

5.10 Changes to 10 CFR Part 21 – Reporting of Defects and Noncompliance

Comment 007-3: Several commenters opposed the proposed changes to Part 21, which would expand the applicability of the provisions to applicants. The commenters believed that the changes are contrary to the Energy Reorganization Act, and the expansion of Part 21 is unnecessary, given the provisions in proposed § 52.6(a).

NRC Response: The NRC disagrees with this comment. The proposed rule required applicants for early site permits, design certifications, and standard design approvals to also meet the Part 21 reporting requirements. A detailed discussion on the Commission’s rationale for imposing these requirements is provided in Section V.J of the Federal Register notice (Supplementary Information).

Part 21 and ESPs

Comments 007-4 and 005-2: Several commenters stated that given the absence of design information for ESPs, which do not require designation of a specific design to be located on the site in question, Part 21 should not be applicable to an ESP applicant or an ESP holder. Commenters argued that under Part 21, only noncompliances and defects in basic components involving “substantial safety hazards” were reportable. They stated it might be impossible for an ESP applicant or holder to determine whether a particular deficiency or noncompliance in siting information created a “substantial safety hazard” because it may not have a design against which to make the determination. They stated that a nonconservatism or error in siting issues does not create a substantial safety hazard, because plant designs typically include significant margins to account for such errors. Commenters believed that absent final design information, an error in siting information would not meet the definition of a reportable condition, and there would therefore be no practicable method for ESP applicants or holders to determine whether an error in siting information created a substantial safety hazard.

NRC Response: The Commission proposed Part 21 reporting requirements on applicants for early site permits, design certifications, and standard design approvals in the proposed rule. A

detailed discussion on the Commission's rationale for imposing these requirements in the final rule is provided in Section V.J of the supplementary information in the Federal Register Notice.

Part 21, Section 50.55(e), and Section 52.6(b) and the Period Prior to Submission of a COL Application

Comment 007-5: Several commenters believed provisions in Part 21, § 50.55(e), and § 52.6(b) would impose “inappropriate and inconsistent” reporting obligations on ESP holders, holders of standard design approvals, and design certification applicants during the period from issuance of the NRC approval to the time of reference of the approval in a COL application. The commenters cited the Supplementary Information accompanying the proposed rule (71 FR 12818) in which the NRC noted that it has changed its position from the 2003 Notice of Proposed Rulemaking and provided the reasons why. The commenters countered that the “regulatory life” of an early site permit, standard design approval, and standard design certification had no regulatory significance until and unless one of the Part 52 actions was referenced in a COL application. They submitted that no “substantial safety hazard” could exist unless and until those actions were referenced in a COL application, making it “unduly burdensome” for these entities to maintain a reporting program when no activities could create a substantial safety hazard under § 206 of the ERA.

Commenters stated that it was not necessary for an ESP applicant to identify any particular design, and, even if a design were specified, it was possible that the design would not have been fully developed at the time the ESP was issued. They noted that under such circumstances, it likely would be impossible for an ESP holder to determine whether a particular deficiency or noncompliance created a “substantial safety hazard.” As a result, the commenters believed it would be impossible for an ESP holder to determine whether to report the deficiency or noncompliance under Part 21, § 50.55(e), or § 52.6(b). The commenters noted that NRC appeared to recognize this point (Supplementary Information at 71 FR 12820) but had not crafted the proposed rule to accommodate it. The commenters mentioned that in particular, there was nothing in the proposed provisions in Part 21, § 50.55(e), or § 52.6(b) that would allow an applicant for design certification or design approval or an ESP holder to defer reporting until such time that the standard design or ESP was referenced in a COL application. They argued the proposed rule must be modified to make it consistent with the accompanying guidance and Supplementary Information.

Commenters believed that it would be “inappropriate” for the NRC to apply Part 21 to the applicant for a design certification. They noted a design certification was a rule, not a license, and the design certification applicant would have no proprietary interest in the design certification rule. They contended that the design certification applicant should have no responsibilities under Part 21 because they might not be the vendor used by the COL applicant. Furthermore, the commenters stated that both Part 21 and § 206 applied to companies supplying basic components for a nuclear plant, meaning that if the design certification applicant contracted with the COL applicant to supply basic components, the design certification applicant would be covered by the “flow down” provisions in Part 21.

Commenters contended that the extension of NRC’s reporting requirements implementing § 206 of the ERA to Part 52 licensing and approval processes should be consistent with three key principles: (1) NRC regulatory requirements implementing § 206 of the ERA should be a

legal obligation throughout the entire “regulatory life” of a NRC license, a standard design approval, or standard design certification; (2) reporting of defects or failures to comply with associated substantial safety hazards should occur whenever the information on potential defects would be most effective in ensuring the integrity and adequacy of the NRC’s regulatory activities under Part 52 and the activities of entities subject to the Part 52 regulatory regime; and (3) each entity conducting activities within the scope of Part 52 should develop and implement procedures and practices to ensure that it fulfills its § 206 of the ERA reporting obligations in an accurate and timely manner.

NRC Response: The NRC agrees, in part, with this comment. The NRC’s implementation of Section 206 of the ERA is consistent with the three key principles, which are discussed in Section V.J of the Federal Register notice (Supplementary Information). Regarding the second principle, reporting may be delayed if there is no immediate consequence or regulatory interest in prompt reporting and delayed reporting will occur when it is necessary to support effective, efficient, and timely action. Therefore, the reporting of defects or failures to comply may be delayed until the time that the Part 52 process (design approval, design certification, or ESP) is first referenced. However, the NRC does not agree with the commenter’s claim that a design certification applicant should have no responsibilities under Part 21. The design certification applicant has supplied the design information and bases for the certified design and the NRC and any applicant or licensee referencing the certified design need to be notified of defects regardless of whether that applicant is the selected vendor for the applicant or licensee that has referenced the design certification.

Part 21 Retroactive Application to Existing ESP Applicants and Design Certification Applicants

Comment 007-6: Several commenters believed that the proposed changes to Part 21 would impose retroactive obligations on the existing ESP and design certification applicants. They listed several reasons why such retroactivity would be inappropriate:

(1) Application of the proposed provision to existing applicants would be unworkable, since they have already issued contracts and cannot reasonably amend them to impose Part 21 responsibilities on contractors and subcontractors.

(2) Imposition of this proposed provision on the existing contracts of applicants would constitute an unconstitutional ex post facto regulation under Article I, Section 9 of the U.S. Constitution.

These commenters argued that the NRC, at a minimum, needed a grandfather clause to exempt existing applicants from the need to meet the new requirements as applied to contracts and activities entered into prior to the effective date of the new regulation.

NRC Response: The Commission proposed Part 21 reporting requirements on applicants for early site permits, design certifications, and standard design approvals in the proposed rule. A detailed discussion on the Commission’s rationale for imposing these requirements in the final rule is provided in Section V.J of the supplementary information in the Federal Register Notice.

Part 21 and Manufacturing Licenses

Comment 005-21: A commenter expressed confusion as to how Part 21 would apply to a ML

until the manufactured reactor was installed in a nuclear power plant. The commenter was also unclear as to how the NRC could equate issuance of an ML with “construction” on p. 12820 because nothing would be constructed until the reactor was transported to and installed in a plant.

NRC Response: The holder of a manufacturing license should consider itself equivalent to the holder of a construction permit with respect to the reactor being manufactured, for purposes of determining its obligations under 50.55(e) and Part 21. For example, with respect to design, the holder of a manufacturing license is responsible for evaluating any defects in the design of the reactor to be manufactured (as approved in the manufacturing license), in order to determine if reporting is necessary under 50.55(e). Similarly, with respect to a manufacturing - e.g., welding of a reactor vessel nozzle - the holder of the manufacturing license is responsible for evaluating any defects in that welding, in order to determine if reporting is necessary under 50.55(e).

The fact that the holder of a manufacturing license does not “construct” the nuclear power reactor is of no consequence in the application of the reporting requirements imposed by Section 206 of the Energy Reorganization Act of 1974, as amended, inasmuch as the requirements imposed by Section 206 do not depend upon whether an activity constitutes or otherwise involves “construction.”

5.11 Changes to 10 CFR Part 25

No comments received.

5.12 Changes to 10 CFR Part 26

No comments received.

5.13 Changes to 10 CFR Part 51 – Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions

NEPA and Connected Actions

Comments 002-3, 002-6, 002-7, 002-8, and 012-1: Several commenters believed that an ESP and COL met the National Environmental Policy Act (NEPA) definition of “connected actions,” and should therefore not require the preparation of a new EIS for the second of the two connected actions, or a revalidation of previous findings if neither the applicant nor others identify significant new information. Commenters stated that under applicable case law, there was no requirement to prepare a new EIS for the latter of the two connected actions that were previously evaluated together in a single EIS. The commenters stated that the EIS prepared at the ESP stage serves as the EIS for issuance of both the ESP and COL. Commenters stated that the ESP EIS included an evaluation of the environmental impacts related to issuance of a COL inasmuch as it considered the environmental impact of plant construction and operation, and thus existing Part 52 regulations properly recognize that a COL application “need not contain information or analyses submitted to the Commission in connection with the ESP” (10 CFR 52.79(a)(1)). One commenter stated the following: “As a threshold matter, the CEQ regulations are not binding on the NRC as an independent agency when the agency has not

expressly adopted them.” (Limerick Ecology Action, Inc. v. NRC, 869 F.2d 719,725,743, 3d Cir. 1989; 49 FR 9352, March 12, 1984). The commenter contended that the CEQ regulations explain that connected actions “mean that they are closely related and therefore should be discussed in the same impact statement” (40 C.F.R. § 1508.25(a)(1)). Since an ESP is a partial construction permit and resolves whether a site is suitable for construction and operation of new units, it is obviously closely related to a COL. Further, under the CEQ regulations, actions are connected if they are “interdependent parts of a larger action and depend on the larger action for their justification” (40 C.F.R. § 1508.25(a)(1)(iii)). If a COL is a partial construction permit, it is obviously an initial step in a larger action and is undertaken only to further decisions and actions on whether new nuclear units should be built. Under applicable case law, there is no requirement to prepare a new EIS for the latter of two connected actions that were previously evaluated together in a single EIS. (Village of Grand View v. Skinner, 947 F.2d 651, 656-57, 2d Cir. 1991)

Several commenters stated that for COL applications that reference an ESP, a supplemental EIS that incorporates by reference the findings and conclusions of the ESP final EIS should be permissible when new significant information has been discovered. The commenters stated that this would be consistent with the proposed new § 51.75(c)(1). To promote better understanding of when certain documents are appropriate, commenters suggested the NRC clarify that § 51.20(b), both existing and proposed, allows preparation of either an EIS or an EIS supplement for both an ESP application and a COL application.

NRC Response: The Commission does not agree with the commenters’ analysis. The commenters’ argument appears to assume in general that if two Federal actions are connected and the EIS prepared for the first action is complete and accurate, then a second EIS need not be prepared for the second action. While the Commission does not disagree with this general argument, the Commission, for two reasons, does not believe it will apply in all circumstances in which a COL application references an ESP.

First, in accordance with 10 CFR 51.50(b), an ESP applicant need not address the economic, technical, and other benefits and costs of the proposed action, or an analysis of other energy alternatives. If an ESP applicant chooses to omit this information from its Environmental Report, the NRC will not address it in the ESP EIS. Thus, the ESP EIS may not be complete with respect to the benefits and costs of the proposed action or energy alternatives, and a supplement to the EIS would then be necessary to discuss such matters if a COL application references the ESP. The commenters do not cite any case to address this situation.

Second, between the time the NRC issues an ESP EIS and a COL applicant references the ESP, significant information not reflected in the ESP EIS may be identified. In light of that significant new information, the ESP EIS would thus not be accurate with respect to the construction and operation of a power reactor proposed in the COL application, and a supplement to the ESP EIS would then be necessary. The commenters acknowledge this principle, and agree that a supplemental EIS should be prepared in connection with the COL application if new and significant information is identified.

The Commission concludes that treatment of an ESP and a COL application referencing that ESP as connected actions does not appear to negate the need for preparing an EIS supplement in connection with the COL application in at least some circumstances. The NRC continues to believe that it is not necessary to require that all topics be covered in a single EIS

at the ESP stage, and that topics such as alternative energy sources and need for power may be treated in an EIS supplement at the COL application stage when the detailed planning for the project is completed. As the commenters note, new and significant information may also prompt the preparation of a supplement to the ESP EIS in connection with the COL application. The Commission has modified the final rule to limit the preparation of a supplementary EIS to those situations. Since the Commission believes that some issues may not be ripe for consideration at the ESP stage, as explained above, and an ESP EIS need not address such issues, the Commission is declining to take a position on whether the granting of an ESP and the granting of a COL referencing that ESP are connected actions.

Nonetheless, if detailed planning and associated environmental information is in fact complete when an ESP application is filed, there is no bar to the NRC to prepare, at the ESP stage, an EIS that resolves all environmental matters associated with construction and operation of a power reactor at the ESP site, including the benefits of such construction and operation (e.g., need for power), and alternative energy sources. The Commission may then rely on that EIS at the COL stage, provided that new and significant information has not been identified. The Commission need not label the ESP and COL as connected actions to adopt this procedure. Accordingly, the NRC has modified the final rule to allow for an ESP EIS to serve as the EIS for a COL application referencing the ESP without supplementation under such circumstances.

NEPA Non-compliance

Comments 008-5 and 011-18: Several commenters expressed concern that the proposed rules would not require a new NEPA process for COL applicants citing an ESP. Commenters stated they were unsure whether NRC was living up to its obligations under NEPA by not taking a “hard look” at both actions separately.

NRC Response: The final rule does provide a “NEPA process” for COL applications referencing an ESP. The NEPA process employed to evaluate issuance of a COL (in 10 C.F.R. § 51.75(c)) will ensure that the NRC takes a hard look at all the environmental impacts resulting from facility construction and operation, which are the impacts associated with COL issuance. The Commission anticipates that it will evaluate the bulk of these impacts in the ESP EIS, leaving only a limited scope of issues for NRC evaluation at the COL stage, along with any new and significant information identified in the interim. At the COL stage, however, there is no need to re-evaluate an impact that was fully evaluated at the ESP stage and for which new and significant information has not been identified. To do so would be to waste the resources of all stakeholders and would not further the purposes of NEPA. Accordingly, if the ESP EIS resolves all environmental issues and no new and significant information has been identified at the COL stage, the ESP EIS will serve as the COL EIS. Under such circumstances, the NRC NEPA process at the COL stage will inquire into whether there is any new and significant information on the matters discussed in the ESP EIS. If new and significant information is identified at the COL stage, a supplemental EIS will be developed to evaluate that information.

While the commenters appear to believe that separate EISs are required for each of the proposed actions (issuance of an ESP and a COL with respect to the ESP site), NEPA does not require this. Rather, the Part 52 licensing model, with respect to ESPs and COLs referencing them, is akin to evaluation of a project at an early stage, with subsequent evaluation at a later stage, as described in the CEQ regulations at 40 C.F.R. § 1508.28(b). As indicated in

§ 1508.28(b), such a process is appropriate when it helps the agency to focus on the issues that are ripe for decision and exclude from consideration issues already decided or not yet ripe. The Commission intends to focus its environmental reviews in a similar manner. Accordingly, the Commission concludes that the final rule will ensure compliance with NEPA.

Comment 005-27(b): A commenter noted that NRC indicates that the environmental impacts associated with the manufacture of a reactor under an ML are not relevant to the NRC's determination; however, the hearing for an ML would consider "environmental, technical, economic, and other" issues associated with SAMDAs. Moreover, the rule would require a finding as to whether the NRC staff has been able to identify "all reasonable SAMDAs" for such a reactor. The commenter asked what standard NRC will use to determine what is a "reasonable SAMDA?" The commenter stated that, to the extent that similar language appears in other parts of new or revised sections of 10 CFR Part 51 (or other parts of 10 CFR), it should be removed.

NRC Response: The Commission disagrees with the commenter's suggestion that the requirements for consideration of severe accident mitigation design alternatives (SAMDAs) be removed from § 51.105a. The only reason provided by commenter in support of its proposal is that the rule does not specify what "reasonable" SAMDAs should be considered. The Commission believes that the Commission's determinations with respect to consideration of SAMDAs in the four final standard design certifications approved by the Commission, the NRC's caselaw on consideration of SAMDA in operating license proceedings throughout the years, and more general federal caselaw on "reasonable alternatives" under NEPA, are sufficient yardsticks for determining the proper scope of SAMDAs for a manufacturing license. No changes were made to the final rule as the result of this comment.

Comment 007-50: Several commenters objected to the proposed changes to §§ 51.105, 51.105a, and 51.107 that identify the contents of notices of hearings for construction permit, ESP, and COL proceedings, including findings to be made by the presiding officer in those proceedings. The changes do not fully incorporate the NRC's conclusions in its Memorandum and Order CLI-05-17 (July 28, 2005) as to the findings that must be made by the Atomic Safety and Licensing Board for a mandatory hearing. Additionally, the proposed rule does not explain why additional findings should be added to the notice of hearing.

NRC Response: The Commission agrees with the commenter that the proposed change to do not change, or repeat, the "ambiguous" language in that was the subject of the Commission's order in Exelon Generation Co., LLC (Early Site Permit for Clinton ESP Site) , et al., CLI-05-17, 62 NRC 5 (2005). The Commission's view is that its decision is sufficiently clear that changes to the rule language which were the subject of the Commission's order, would re-introduce some uncertainty into the regulations. Hence, the Commission did not revise the language to "conform" to the Commission's decision on the distinction between contested versus uncontested "issues," the Commission's admonition against de novo review of uncontested issues by the presiding officer, and the prohibition against an intervenor's prohibition on uncontested matters. On these matters, CLI-05-17 provides clear direction. The Commission believes that a generic change should be accomplished in § 2.104 for all proceedings - not just proceedings involving Part 52 permits and licenses, and such rulemaking is outside the scope of the Part 52 rulemaking. Accordingly, the Commission declines to adopt the commenter's proposed changes to § 2.104.

In retrospect, the Commission agrees with the commenter that the SOC for the proposed rule did not provide rationales for adopting additional findings with respect to the various Part 52 permits and licenses. To explain, the Commission's intent was to ensure that the required findings, as set forth in §§ 2.104, 51.105, 51.105a and 51.107, are consistent with the necessary findings which must be made under relevant provisions of the AEA. For example, the findings on early site permits (which may include ITAAC) and combined licenses include a finding with respect to ITAAC, are required by or are consistent with Section 185.b.; and the findings on "technical qualifications" are required by, or are consistent with § 182.a of the AEA. In addition, the Commission added language that reflects the findings set forth in §§ 52.24 and 52.97. For example, the proposed § 2.104(d)(1)(ii) finding specified for early site permits on necessary notifications is drawn from current § 52.24 (which was proposed to be retained in proposed § 52.24(a)(2)). The Commission does not regard the incorporation of the findings in §§ 52.24 and 52.97, which have already been approved by the Commission in the 1989 Part 52 rulemaking, as either expanding or contracting in any substantive manner the issues for which findings must be made under § 2.104, or otherwise introducing a new legal problem or ambiguity. The commenters do not appear to have identified any specific legal problem with the proposed findings; rather, they were simply seeking Commission explanation for the changes. Accordingly, the Commission has not made any changes to the final rule as a result of these comments. However, if any commenter, upon reflection, believes that there is a new legal problem introduced by the changes to § 2.104, they may submit a petition for rulemaking requesting the Commission to correct the matter.

Comment 007-60: Several commenters suggested that proposed § 51.71(d) should be made consistent with § 51.50(c)(1)(i). COL applicants that reference an ESP are not required to demonstrate that "the site falls within the site characteristics specified within the early site permit."

NRC Response: NRC Response: The NRC agrees and has removed the referenced language in the final rule.

Comment 007-66: Several commenters recommended that proposed §§ 51.50(b) and 51.71(d) be revised to refer to characteristics that fall within the "site characteristics and design parameters," rather than "site parameters."

NRC Response: The NRC agrees that the proposed rule language referenced by the commenter should be revised and has done so in the final rule.

Comment 007-85: Several commenters supported the proposed changes to §§ 51.50, 51.71(d), and 51.75(c)(1).

NRC Response: No response necessary.

Comment 008-3: A commenter believed that the NRC should demand that applicants consider only good sites and then choose one of the best sites they considered. Sites with problems should not be approved.

NRC Response: This NRC will not approve any site for eventual construction and operation of a nuclear power plant that does not meet NRC regulations.

Comment 011-6: A commenter suggested that §§ 51.50(c)(2) and (c)(3) and 51.75(c)(2) and (c)(3) should explain what to do when sites are not within parameters.

NRC Response: The NRC does not agree that it is necessary to revise §§ 51.50(c)(2) and (c)(3) and 51.75(c)(2) and (c)(3) to explain what to do when a COL applicant that references either a design certification or a manufactured reactor cannot demonstrate that the site characteristics for the COL site fall within the site parameters postulated in the design certification or manufacturing license. The NRC believes this level of information is more appropriate for inclusion in regulatory guidance documents such as Draft Regulatory Guide (DG) 1145, “Combined License Applications for Nuclear Power Plants (LWR Edition).”

Comment 011-7: One commenter believed that §§ 51.50(c)(1) and 51.71(d) should refer to information on issues that were “not resolved.”

NRC Response: The NRC agrees with the commenter and has revised the rule text in proposed §§ 51.50(c)(1) and 51.71(d) [final § 51.75(c)(1)] to refer to issues “not resolved in the early site permit proceeding.”

Comment 011-8: A commenter noted that §§ 51.50(c)(1)(iii), 51.71(d), 51.75(c)(1), and 51.107(b) require applicants to submit new and significant information on the site or design, but the commenter asked about changes offsite affecting the environmental impacts.

NRC Response: The requirement to submit new and significant environmental information has been modified in the final rule based, in part, on public comments. The Commission believes that the changes that occur offsite, which could affect the analysis of environmental impacts of construction and operation considered in the ESP, need to be considered to determine whether the new information is relevant to the NRC’s prior analysis and whether it is also significant. The rule language has been modified to capture this concept. In the final rule, the requirement is that COL applicants referencing an ESP must submit any significant new information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding. This revised wording does not limit the new and significant information to the site or design, but rather, focuses on issues resolved in the ESP proceeding.

Comment 011-9: A commenter referred to § 51.50(c) (page 12880), and asked if the second sentence in this section should include the phrase “as modified in this paragraph...,” similar to § 51.50(b).

NRC Response: The NRC agrees with the commenter and has revised the first sentence in § 51.50(b) to include the phrase “as modified in this paragraph,” such that the final provision reads, “Each applicant for an early site permit shall submit with its application a separate document, entitled “Applicant’s Environmental Report–Early Site Permit Stage,” which shall contain the information specified in §§ 51.45, 51.51, and 51.52, as modified in this paragraph.”

Comment 011-10: A commenter believed that the change in § 51.53(c)(3) to include holders of a combined license issued before June 30, 1995, appears nonsensical because there are not any combined license holders.

NRC Response: While there are no plants with a combined license issued before June 30,

1995, the date in this portion of the rule relates to the effective date of the Generic Environmental Impact Statement for License Renewal of Nuclear Plants (GEIS, NUREG-1437); the GEIS provides the basis for the analysis of environmental effects of license renewal. Therefore, whenever the GEIS is updated and the results of the update is codified in an amended rule, this date will change. The reason that this section was changed at this time was to ensure that a license holder of a COL could also seek license renewal under the provisions of 10 CFR Part 54; the environmental effects of license renewal for a plant authorized to operate under a combined license would also be considered in the periodic updates to the GEIS; this ensures that combined licenses can be renewed in the same way as operating licenses provided that the facility was considered in the GEIS.

Comment 011-11: A commenter asked whether § 51.71(d) should refer to an “obviously superior” alternative site.

NRC Response: The NRC agrees that the subject provision in proposed § 51.71(d) [final § 51.75(b)] should refer to an “obviously superior” alternative site. The NRC has revised this provision in the final rule to read, “The draft environmental impact statement must focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the site characteristics, and need not include an assessment of the benefits (for example, need for power) of the proposed action or an evaluation of other alternative energy sources unless considered by the applicant, but must include an evaluation of alternative sites to determine whether there is an obviously superior alternative to the site proposed.”

Comment 011-12: A commenter noted that § 51.71(d) (page 12882) refers to a supplemental EIS used for a COL referencing an ESP. The commenter disagreed and does not believe it should be a supplemental EIS because the regulations elsewhere appear to require a complete EIS for a COL. The commenter noted that the wording about a supplemental EIS appears elsewhere in the rule as well.

NRC Response: The Commission does not agree with the commenter that the regulations require a completely new EIS at the COL stage when the applicant is referencing an ESP. To the extent existing regulations are unclear on this point, the Commission has made changes to make explicit that only a supplement to the ESP EIS need be prepared if the COL application references an ESP. Further, the Commission has added provisions to allow the ESP EIS to serve as the COL EIS under certain limited circumstances, as discussed below.

In most circumstances, the NRC will prepare an EIS supplement in connection with a COL application referencing an ESP and not an entirely new EIS. The NRC believes that topics such as alternative energy sources and need for power may be deferred at the ESP stage and treated in an EIS supplement at the COL application stage when the detailed planning for the project is completed. Similarly, an ESP applicant need only submit information on the effects of facility construction and operation to a depth sufficient to evaluate alternative sites, and an EIS supplement may then be necessary at the COL stage to fully disclose all impacts. Also, between the time the NRC issues an ESP EIS and a COL applicant references the ESP, significant information not reflected in the ESP EIS may be identified. In all these circumstances, which the Commission anticipates will be the usual case, the NRC will prepare a supplemental EIS. Nonetheless, if detailed planning and associated environmental

information is in fact complete when an ESP application is filed, there is no bar to the NRC to prepare, at the ESP stage, an EIS that resolves all environmental matters associated with construction and operation of a power reactor at the ESP site, including the benefits of such construction and operation (e.g., need for power), and alternative energy sources. The Commission may then rely on that EIS at the COL stage, provided that new and significant information has not been identified. The NRC believes that it would be satisfying its obligations under NEPA and NRC regulations whether the NRC prepares a supplement to an ESP EIS or not, as circumstances warrant. The NRC has made amendments in the final rule to clarify the requirements to reflect the above discussion.

Comment 011-13: A commenter suggested that the wording of the footnote in § 51.71(d) (page 12883) implies that an impact assessment was available, but then was withdrawn. The commenter suggested revising the language so that it says “is not available from...”

NRC Response: This change to the footnote was unintended. The final rule language preserves the original structure and language.

Comment 011-14: A commenter stated that § 51.75(a), (b), and (c) of the rule is not clear how fuel cycle impacts are handled if the plant design is outside the bounds of Table S-3.

NRC Response: The environmental effects involved in the fuel cycle must be considered for a production and utilization facility; consequently, every environmental report prepared for the construction permit stage (i.e., a CP, an ESP, or a COL) must provide the environmental data and analyze the effects. The bases for considering environmental effects for light-water reactors are prescribed in § 51.51(a). If the plant design attributes for a light-water-cooled nuclear power reactor are not within the environmental data provided in Table S–3, then the environmental report should include a discussion of the significance of the departure. In the case of an other-than-light-water-cooled nuclear power reactor, Table S–3 does not apply and the applicant would need to provide a full description and detailed analysis of the environmental effects of the fuel cycle.

Comment 001-15: A commenter wondered why Table S-4 is not mentioned.

NRC Response: The Commission established the conditions that allows applicants to consider the environmental effects of transportation of fuel and waste codified in Table S–4. While § 51.52 indicates that the applicant’s environmental report must take this information as the basis for its analysis, for reactors that do not meet the conditions enumerated in § 51.52(a), the environmental report would need to provide a full description and detailed analysis of the environmental effects.

Comment 011-16: A commenter asked whether the NRC must determine in § 51.75(c)(1), (2), and (3) that previous analyses are applicable.

NRC Response: Yes, the NRC must determine the applicability of previous analyses, data, and information that can be considered both by applicants and the NRC staff. In the end, as stated in § 51.70(b), the NRC staff will independently evaluate and be responsible for the reliability of all information used in the draft environmental impact statement. Consequently, the applicability and reliability of previous analyses, data, and information must be evaluated.

With respect to the NRC's compliance with the National Environmental Policy Act (NEPA), under the provisions of § 51.29(a), the NRC would use the scoping process to "identify and eliminate from detailed study those issues which are peripheral or are not significant or which have been covered by prior environmental review" and to identify other environmental assessments and impact statements which are "related to but are not part of the scope of the statement under consideration." Tiering allows federal agencies to rely on previous environmental assessments (EAs) and EISs to aid in the presentation of issues, eliminate repetition, or reduce the size of an EIS. The regulations permit the NRC staff to use tiering and incorporation by reference [see 10 CFR Part 51, Subpart A, Appendix A.1.(b)] principles. Analyses, data, and information that existed from prior licensing decisions can be used by the NRC staff provided that it was demonstrated to be reliable and technically applicable to the prospective licensing action.

Comment 011-17: A commenter noted that § 51.107(b) (page 12885) addresses issues "accorded finality under 52.39..." The commenter felt that this wording is not consistent with other sections. The commenter suggested rewording as follows: "issues resolved in the proceeding on the application for issuance of the early site permit..." to be consistent with § 52.39.

NRC Response: The NRC agrees and has revised the language in proposed § 51.107(b) to be consistent with the language in § 52.39 in the final rule.

5.14 Changes to 10 CFR Part 54

No comments received.

5.15 Changes to 10 CFR Part 55

No comments received.

5.16 Changes to 10 CFR Part 72 – Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste and Reactor Related Greater than Class C Waste

No comments received.

5.17 Changes to 10 CFR Part 73 – Physical Protection of Plants and Materials

Comment 007-86: Several commenters supported the proposed changes to §§ 73.56 and 73.57.

NRC Response: No response necessary.

5.18 Changes to 10 CFR Part 75

No comments received.

5.19 Changes to 10 CFR Part 95

No comments received.

5.20 Changes to 10 CFR Part 140 – Financial Protection Requirements and Indemnity Agreements

Comment 007-71: Several commenters believed that the proposed rule adequately addresses the issue of adding Part 52 applicants and license holders to the scope of Part 140.

NRC Response: No response necessary.

5.21 Changes to 10 CFR Part 170

No comments received.

5.22 Changes to 10 CFR Part 171 – Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Material Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Listed by NRC

Comment 007-72: Several commenters believed that the proposed rule adequately addresses the issue of modifying § 171.15 to reflect that a COL holder shall start to pay annual fees once the Commission has made the finding under § 52.103(g).

NRC Response: No response necessary.

Comment 007-87: Several commenters supported the changes to Part 171.

NRC Response: No response necessary.

5.23 Other General Comments

Comment 008-1: A commenter remarked that it was sensible to change the design certification process now because NRC has learned something over the years. However, the commenter pointed out that it is unknown at this time what a properly-prepared site permit or a combined construction permit and operating license will look like. The commenter asked why NRC hasn't published an example prior to requesting comment on the proposed rule, and argued that the public is not well informed if an example is not published. The commenter questioned whether the permits and licenses are going to be nonspecific, beneficial deals for the industry or specific enough so industry is held accountable for their performance.

NRC Response: This comment addresses issues that are outside of the scope of this rulemaking. The NRC notes that a sample combined license can be found in SECY-00-0092, "Combined License Review Process," dated April 20, 2000 and a sample early site permit can be found in a June 22, 2004 NRC letter to the Nuclear Energy Institute (ML041110012).

Comment 008-4: This commenter was supportive of NRC's plan to treat an approved design

as a final design without changes. However, the commenter noted that it is not clear that it will always do so because of the potential for severe environmental events or changes (e.g., tsunamis, earthquakes, and hurricanes). The commenter asked how these changes could impact the utility of emergency plans prepared years earlier. The commenter also pointed out that population growth is another change that should be considered to ensure old plans (i.e., more than 25 years) are still effective.

NRC Response: This comment addresses issues that are outside of the scope of this rulemaking. However, the NRC notes that if changes to communities or landscapes have occurred over time following the initial review and approval of emergency plans, the rules require that the earlier approved plans must be updated and/or corrected, if needed, to ensure that they continue to comply with the applicable regulatory requirements.

Comments 003-5: If NRC determines that any of the public comments raise re-notice questions under the APA, several commenters urged the Commission to initiate an expedited rulemaking to ensure that any new rule associated with new plant licensing is completed prior to the submittal of the first COL applications. The commenters want in place as soon as possible a more efficient, less time-consuming licensing and hearing process.

NRC Response: The NRC has determined that one set of changes in response to comments, relating to revision to the LWA process in 10 CFR 50.10, require renoticing. The NRC published a supplementary proposed rule on the LWA process in October 2006.

Comment 005-17: A commenter encouraged the NRC to review those elements of the rules (e.g., Part 50, Part 52) related to financial qualifications and other issues that may be addressed in the Energy Policy Act of 2005. If changes are required to comply with the Act, it would be preferable to incorporate them into this action rather than undertaking a separate rulemaking that would delay their implementation.

NRC Response: The Commission disagrees with the commenter's suggestion. There are many ongoing NRC activities addressing compliance with the Energy Policy Act of 2005, most of which are unrelated to the Part 52 rulemaking. It would be disruptive of the regulatory process to incorporate them into his rulemaking. However, the Commission agrees that regulatory language in the Part 52 rulemaking should be consistent with the Energy Policy Act. The Commission has ensured that provisions in the final rule are consistent with the Energy Policy Act of 2005.

Comments 006-6 and 010-2: Two commenters argued that if the proposed rule is adopted in its present form, it would represent a retreat from the NRC quest for finality in the early site permit, design certification, and combined license processes. One commenter (010), believed that some of the regulatory changes and their timing will erode predictability in the regulatory process and will decrease effectiveness, and cited, as an example, changes which eliminate the requirement for the Commission to treat as resolved those issues previously resolved in an Early Site Permit proceeding.

NRC Response: The NRC's final rule contains changes which address, to some extent, the commenters' concerns. However, the NRC believes that the final rule is consistent with the Commission's original vision for Part 52, but reflects lessons learned from the review of four

design certification applications, three early site permit applications, and the development to date of pre-application guidance for combined licenses, as well as being consistent with applicable law.

Comments 009-4, 014-1, 014-2, 015-1, 016-1, and 017-1: Commenters endorsed the NEI letters submitted to the NRC regarding the proposed rule. Commenters expressed their full support for the NEI recommendations contained within the letters, and stated the importance of the NEI's recommendations and amendments to the efficiency and predictability of their industries. The commenters stated their support of the coordinated efforts by the NRC staff and the industry to ensure an efficient and effective licensing process. One of the commenters also strongly supports the NEI comments related to the timing of final regulations.

NRC Response: No response necessary.

Comment 018-1: The commenter commended NRC's efforts in preparing this proposed rule that enhances its effectiveness and efficiency in implementing its licensing and approval processes. The commenter supported the NRC's approach of addressing the applicability of various requirements to each of the licensing processes (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license).

NRC Response: No response necessary.

6 Availability of Documents

No comments received.

7 Agreement State Compatibility

No comments received.

8 Plain Language

No comments received.

9 Voluntary Consensus Standards

No comments received.

10 Environmental Impact-Categorical Exclusion

No comments received.

11 Paperwork Reduction Act Statement

No comments received.

12 Regulatory Analysis

No comments received.

13 Regulatory Flexibility Certification

No comments received.

14 Backfit Analysis

No comments received.

Appendix A: Comment Numbers, Commenter Names and Organizations, and Issues Commented On

Comment Number	ADAMS Accession No.	Commenter Name	Organization	Issue Outline Sections
001	ML061310166	Schaefer, Kurt	A&K Nuclear Licensing Inc.	5.3.3, 16
002	ML061370648	Heymer, Adrian	Nuclear Energy Institute	4.9
003	ML061460167	Heymer, Adrian	Nuclear Energy Institute	4.12, 4.12, 5.6, 5.3.4, 16
004	ML061510471	Heymer, Adrian	Nuclear Energy Institute	5.4.2
005 ^a	ML061510474	Gardner, Ronnie	Areva NP	4.13, 4.15, 5.3, 5.6, 5.13, 5.3.3, 5.3.6, 5.4.3, 5.4.5, 5.4.6, 5.4.7, 5.4.9, 5.4.30, 16
006 ^{a, b, c, d}	ML061510475	Sterdis, Andrea	Westinghouse Electric Company	3, 4.14, 5.10, 5.3.2, 5.3.3, 5.3.4, 5.4.7, 16
007	ML061580572	Heymer, Adrian	Nuclear Energy Institute	3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13, 4.14, 4.15, 5.3, 5.4, 5.6, 5.8, 5.10, 5.13, 5.16, 5.17, 5.20, 5.22, 5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5, 5.3.6, 5.4.2, 5.4.5, 5.4.6, 5.4.7, 5.4.8, 5.4.9, 5.4.10, 5.4.12, 5.4.15, 5.4.19, 5.4.21, 5.4.22, 16
008	ML061510482	Martinez, R.		4.9, 5.13, 7, 16
009 ^{a, b, c, d}	ML061510484	McCabe, Brian	Progress Energy	2, 4.14, 5.3.2, 5.3.3
010 ^{a, b, c, d}	ML061510487	Keuter, Dan	Entergy Nuclear Inc.	4.9, 16
011	ML061510489	Neenan, Frances		4.9, 5.13, 5.3.2, 5.3.4
012 ^a	ML061530400	Grecheck, Eugene	Dominion Nuclear	4.9, 5.13, 5.3.2, 5.3.4
013 ^{a, b, c, d}	ML061560023	Stall, J.A.	Florida Power and Light Company	4.8, 4.12, 5.6, 5.3.2, 5.3.3, 5.3.4, 5.4.2
014 ^a	ML061590278	Kray, Marilyn	NuStart Energy	2, 5.3, 16
015 ^a	ML061590292	Kray, Marilyn	Exelon Generation	2, 5.3
016 ^a	ML061590086	Miller, J.A.	Southern Nuclear Operating Company, Inc.	2, 5.3, 5.3.3
017 ^a	ML061590087	Krich, R.M	UniStar Nuclear	2
018	ML061590088	Norton Miller, Ann	United States Environmental Protection Agency	16
019	ML061640247	Quinn, Vanessa E.	United States Department of Homeland Security	N/A

^a Commenters 006, 009, 010, 012, and 013 also fully endorsed and supported NEI's comments submitted on May 16, 2006. Therefore, all of these commenters are included in each of NEI's May 16, 2006 comments (comment number 002).

^b Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI's comments submitted on May 25, 2006. Therefore, all of

these commenters are included in each of NEI's May 25, 2006 comments (comment number 003).

- ^c Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI's comments submitted on May 25, 2006. Therefore, all of these commenters are included in each of NEI's May 25, 2006 comments (comment number 004).
- ^d Commenters 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017 all fully endorsed and supported the Nuclear Energy Institute's (NEI's) comments of May 30, 2006. Therefore, all of these commenters are included in each of NEI's May 30, 2006 comments (comment number 007).