UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SECRETARY

April 11, 2007

COMMISSION VOTING RECORD

DECISION ITEM: SECY-06-0220

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

The Commission (with all Commissioners agreeing) approved a final rule as noted in an Affirmation Session and recorded in the Staff Requirements Memorandum (SRM) of April 11, 2007.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Klein
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons
OGC
EDO
PDR

VOTING SUMMARY - SECY-06-0220

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. KLEIN	X				X	11/29/06
COMR. McGAFFIGAN	X				X	2/13/07
COMR. MERRIFIELD	X				X	1/9/07
COMR. JACZKO	X				X	1/5/07
COMR. LYONS	X				X	12/15/06

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the final rule, as noted in Affirmation Session and reflected in the SRM issued on April 11, 2007.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN KLEIN

SUBJECT: **SECY-06-0220 - FINAL RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS" (RIN AG24)**

Approved xx Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below___ Attached xx None ___

SIGNATURE

Nov. 29, 2006
DATE

Entered on "STARS" Yes ✓ No ___

Chairman Klein's Comments on SECY-06-0220

I approve the staff's recommendation to publish in the *Federal Register* the notice of final rulemaking to update 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," including conforming changes to related sections of the regulations in Title 10, Chapter 1, subject to the following comments. I also approve certifying that this rule 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).

I commend the staff for the extraordinary effort, dedication, and capability they have demonstrated in timely delivery of this final rule to the Commission. The final rule enhances effectiveness and efficiency of the Part 52 licensing processes, and clarifies the applicability of requirements to each of the processes: early site permit (ESP), standard design approval, standard design certification, combined license (COL), and manufacturing license. I understand that there is always room for further enhancements that could be made and that not all stakeholders are fully supportive of every aspect of the rule; however, taken together this rule change will help ensure stability in the new reactor licensing process. Now is the time to make these changes, not while we are in the process of actually reviewing new reactor applications.

I believe that issues should be addressed early in the review process and many of the proposed changes facilitate early resolution of issues. The proposed process for completing the Environmental Impact Statement (EIS) at the Early Site Permit (ESP) stage allows for an ESP EIS to serve as the EIS for a COL application referencing the ESP without requiring supplementation to the ESP EIS. The process provides for achieving ESP finality on environmental issues and allows the agency to meet its obligations under the National Environmental Policy Act where a COL application references an ESP. I also believe that the Design Certification Rule (DCR) amendment process would allow for generic resolutions of design acceptance criteria (DAC), error corrections, or increasing standardization without meeting the special backfit requirement. A DCR amendment to generically resolve DAC 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.

I believe that the new additions to §52.99 requiring submittal of detailed schedule for completing Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) and submittal of notifications related to completed and as-yet uncompleted ITAAC would help to ensure that (1) 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 ITAACs were met and (2) interested persons will be able to meet the Atomic Energy Act, Section 189.a(1) threshold for requesting a hearing related to ITAAC items that they believe have not been sufficiently completed. The final rule language clearly sets the functional requirement in requiring "sufficient information" to demonstrate that ITAAC items were completed and their criteria were met; the statement of consideration adequately describes the basis for the requirement; and the guidance document should explain how the functional requirement could be met. This guidance document should be developed, in consultation with stakeholders, to provide clarity on what would constitute "sufficient information" such that the licensee's "notification" would provide a reasonable basis for a prospective intervener to form judgments about ITAAC completion.

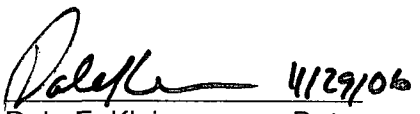
I agree with the staff's proposal to require COL applicants to demonstrate how generic letters and bulletins have been incorporated into plant design and to monitor and evaluate international

operating experience comparable to generic letters and bulletins. The staff should explain in the section-by-section discussion of the *Federal Register Notice* that for plant designs that are based on or are evolutions of plants that have operated in the U.S., the applicant should use NRC's 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. Regarding the requirement to address comparable international operating experience, some future applications may be for designs that are not based on or are not evolutions of plants that have operated in the U.S.; therefore, those applications should address insights from relevant international operating experience.

With respect to the related supplemental proposed rule on limited work authority (LWA), I agree with two points raised in the Nuclear Energy Institute letter of November 16, 2006.

I believe an applicant should be allowed to conduct excavation activities without prior NRC approval. Therefore, "construction" should be redefined to exclude excavation from the list of activities that require an LWA. The following additional rule language should be included. "The term 'construction' excludes excavation for any structure, system or component otherwise included in the term 'construction,' provided the excavations are geologically mapped and the NRC staff is notified when the excavations are open for inspection." This will allow NRC to obtain soil structure information at an early stage.

Lastly, I believe that an LWA application should be allowed to be submitted up to 18 months before a COL application, rather than the current staff proposal of 12 months. Earlier submittal and approval would allow construction to commence earlier and prevent potential unnecessary delay in project schedules. Therefore, the staff should change the requirement to allow an LWA application to be submitted up to 18 months before a COL application.



4/29/06

Dale E. Klein Date

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-06-0220 - FINAL RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS" (RIN AG24)**

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below___ Attached_X_ None ___

Edward McGaffigan Jr.

SIGNATURE

February 13, 2007

DATE

Entered on "STARS" Yes _X_ No ___

Commissioner McGaffigan's Comments on SECY-06-0220

I approve the final rule amending the regulations in 10 CFR Part 52 concerning the licensing and approval processes for nuclear power plants, subject to the changes below.

First, I believe that combined operating license (COL) licensees should be required to maintain a probabilistic risk analysis (PRA) that meets the Commission's stated policy goal, an all modes, all initiating event level 3 living PRA, as soon as practicable. I recall that at the proposed rule stage the staff had wanted to require such a PRA of COL applicants, which the Commission disapproved because it was far beyond the state-of-the-art at this time. Yet the staff now opposes the requirement that COL licensees be required to achieve the Commission's policy on PRA quality (SECY-04-0118). The Advisory Committee on Reactor Safeguards (ACRS) supports my position. If we do not establish this requirement in this rulemaking, we may have forfeited permanently a PRA quality standard for the new plants, because the staff has always been unwilling to require high-quality PRAs of existing licensees because of their interpretation of the backfit rule (10 CFR 50.109). All of the new plants will likely be operating still in 2076, the 100th anniversary of WASH-1400. It would be a sad commentary on our alleged commitment to risk-informed regulation if the Commission is still pleading with licensees then to bring their PRAs to the state-of-the-art. I also support a requirement that COL licensees, once the plant is operating, be required to submit periodic reports on any significant changes to their high quality living PRA, perhaps as part of the FSAR update process.

Second, I agree with the anonymous staffer who wrote the Commission about a last minute change in the rule that would require only the submission of a description of the design-specific PRA, rather than the PRA itself by design certification and COL applicants. As ACRS agreed, to certify a design or approve a COL, a detailed review of the PRA is necessary. Commissioner Jaczko has also supported ACRS. The burden should not be on the staff and ACRS to traipse off to the applicants' facilities to review the PRA. That sounds like a prescription for delaying reviews rather than speeding them up.

Third, I concur with Commissioner Lyons, Commissioner Jaczko and the staff dissenters who raised the issue that an EIS should be completed at the COL stage even if an ESP EIS has already been completed. This was the staff position in the proposed rule and there is no reason for changing it. I am all for finality for issues already resolved at the ESP stage and support the process proposed by Commissioner Lyons for making decisions on "new and significant" information claims on closed ESP EIS issues. But on the issue of an EIS at the COL stage, the only example that worries me is the Vogtle ESP EIS. It makes no sense to be working on two EISs simultaneously, but the solution for contemporaneous ESP and COL applications would appear to be to convert the ESP EIS to a COL EIS upon receipt of the COL application. The Atomic Safety and Licensing Board (ASLB) on the ESP would become the ASLB on the COL. Except in the case of contemporaneous applications, I cannot envision cases where an updated EIS at the COL stage will not be necessary. It should be required.

I agree with the modifications to section 52.99 proposed by Commissioner Lyons and Commissioner Merrifield in their votes, intended to address concerns raised by the Nuclear Energy Institute (NEI) in their December 1, 2006 letter. Section 52.99(a) should be modified by deleting "detailed" and inserting "or at the start of construction as defined in 10 CFR 50.10(b), whichever is later" to provide necessary flexibility to account for potential delays in construction. Consistent with section 185b. of the AEA, section 52.99(b) should be modified to read, "any one of the prescribed acceptance criteria has been met." Section 52.99(c) should also be revised to read "the prescribed inspections, tests and analyses have been performed and that the

prescribed acceptance criteria have been met." In order to avoid any ambiguity in the use of the phrase "sufficient information," section 52.99(c)(1) should be modified to require "a summary description of the bases for the licensee's conclusion that the inspections, tests and analyses have been performed and that the prescribed acceptance criteria have been met." Section 52.99(c)(2) should be modified using similar language to address uncompleted ITAAC.

I agree with the proposed modifications to section 52.63(a)(1) suggested by NEI in its December 1, 2006 letter, to preserve design certification finality. Section 52.63(a)(1)(v) should be modified to make clear the provision which would allow changes to "correct errors in the design certification information" is only to be used to correct a material error, that is an error that significantly and adversely affects a design function or analysis conclusion described in the design control document. The language of section 52.63(a)(1)(v) should be modified to read "Is necessary to correct material errors in the design certification." I also agree that section 52.63(a)(1)(vi) may preclude implementation of necessary changes identified through first-of-a-kind engineering and construction merely because they maintain standardization. It would be more appropriate to allow changes that contribute to increased safety, reliability and/or efficiency in plant design, construction or operation. Section 52.63(a)(1)(vi) should be replaced with a new section, 52.63(a)(2) that would read as follows:

> (a)(2) Subject to the provisions of 10 CFR § 50.109, while a standard design certification rule is in effect under §§ 52.55 or 52.61, the Commission may modify, rescind, or impose new requirements on the design certification, whether on its own motion, or in response to a petition from any person, only if the Commission determines in a rulemaking that the change contributes to increased safety, reliability and/or efficiency in plant design, construction or operation.

I believe we are inappropriately placing the burden on COL applicants to monitor and evaluate generic letters and bulletins issued after the most recent revision of the applicable standard review plan and six months before the submittal date of the application, or comparable international operating experience in 10 CFR § 52.79(a)(37) [a comparable requirement exists for design certification applicants in section 52.47(a)(22)]. Both should be deleted. NRC staff should not be allowed to force applicants to do the NRC's job. Insights from bulletins and generic letters more properly should be incorporated in the SRP and any relevant RGs. The breadth of this requirement also fails to achieve the goal of clarity, allowing misuse (intentional or accidental) of this burden shifting to potentially permit a game of "gotcha" in the future should an applicant fail to take into account some small element of international operating experience.

I join Commissioner Lyons in his recommendation that the modified language contained in the rule in sections 52.17(a)(xii), 52.47(a)(9), and 52.79(a)(41), requiring an evaluation against "NRC's application and review guidance" instead of the SRP alone is improper and should be removed. Generic guidance without acceptance criteria would not serve any useful purpose.

Section 52.79(a)(41) would require evaluation of the facility against the SRP "6 months before the docket date of the application." However, this date is not known to anyone and provides an element of instability. The rule text should explicitly state that the evaluation should be performed "6 months before the date of the application." I recognize that "docket date" is used elsewhere in our regulations, but the mistake should not be propagated here. It should be corrected elsewhere.

With regard to severe accidents, several potential modifications were suggested by NEI in their December 1, 2006 letter, and should be incorporated into the rule text and SOC's. First, the accompanying SOC's should clarify that severe accidents are not design basis accidents within the meaning of 10 CFR § 50.2 and are therefore not subject to same requirements pertaining to SSCs that perform design basis functions. There is potentially ambiguous language in sections 52.47 and 52.79 inferring that there is an open ended universe of severe accidents. Such is not the case, and the staff should not simply rely on referenced guidance documents to make this clear, but should be explicit in the rule text by replacing "e.g." with "i.e." in both sections 52.47 and 52.79. Finally, section VIII.B.5.c should be modified to reflect that our focus in the severe accident change process is on ex-vessel severe accident design features.

I believe that ESPs currently under review should not be required to be modified by this rule. Instead a general grandfathering provision should be included in section 52.17(a) that states, "For applications submitted before [Insert Final Date of Rule], the rule provisions in effect at the date of docketing apply unless otherwise requested by the applicant in writing."

As I have mentioned in previous votes, achieving passage of desired legislation that would hopefully eliminate the anachronistic need for mandatory hearings by the end of next year is probably now impossible, and we may no longer even want to submit the proposal. However, the Commission is not without options that would allow us to streamline the process, create efficiencies, and properly place the primary responsibility in the hands of the Commission which is best equipped to handle this unique action. The Commission, not the Boards, should handle mandatory hearings through paper or legislative style hearings. Development of a process that will work efficiently to deal with potential hearing issues will be of paramount importance, and as Chief Judge Hawkens has recognized, this is not an area of expertise for Boards. The Commission is well equipped, however, to handle this in a prompt manner, ensuring focused analysis of relevant issues at the mandatory hearing stage.

If the Commission is handling mandatory hearings on the COLs there will be absolutely no need for the post-TMI mandatory stay requirement. There is no gain in public confidence by piling delay on delay, quite the contrary. So I strongly support the staff's change to 10 CFR 2.340 for COLs, ESPs and in manufacturing licenses. I would note that equally complex licensing proceedings for enrichment facilities and fuel cycle facilities such as the proposed MOX facility have no Commission stay provision. I would also note that we have delegated dry cask certification, license renewals, power uprates, and numerous comparably important matters to the staff except in contested proceedings.

The text of the final rule should be modified to reflect that the Commission will handle initial determinations as to whether there is a prima facie showing that either one or more of the acceptance criteria in the COL have not been, or will not be met, and the attendant public health and safety consequences of such non-conformance. If the Commission finds that the elements of 10 CFR 52.103(b) have been met, then the Commission will handle resolution of the matter in a legislative style proceeding. This is necessary if the Commission wishes to build in a level of efficiency necessary to meet the statutory deadline of completion within 6 months. Ideally the structure of a hearing where the Commission has not made the initial prima facie finding would allow for referral at that point to a Licensing Board for resolution. However, it may be necessary for the Commission to also handle such hearings on ITAACs to meet the statutory deadline, which does not appear long enough for appeals of Licensing Board decisions to the Commission.

I strongly agree with the removal of the mandatory hearing requirement for manufacturing licenses for the reasons articulated by the staff and amplified by Commissioner Merrifield.

I agree with Commissioner Jaczko that Appendix Q should be deleted as proposed in the proposed rule. The staff is faced with an overwhelming workload for at least the next decade. There is no reason to further burden the staff with site suitability consultations.

I also agree with Commissioner Jaczko that the provision allowing a Part 50 applicant to use portions of the Part 52 process should be eliminated.

I agree with Commissioner Lyons that withholding schedules from public disclosure as proprietary information under 10 CFR 2.390 is a dubious proposition from the point of view of the Freedom of Information Act.

I agree with Commissioner Lyons' comments on section 52.39(c). A contention challenging a variance should demonstrate a substantial underlying safety concern, the same as all contentions.

E McGaffigan Jr. 2/13/07

Edward McGaffigan, Jr. **(Date)**

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-06-0220 - FINAL RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS" (RIN AG24)**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below___ Attached ✓ None ___

SIGNATURE

1/9/07

DATE

Entered on "STARS" Yes ✓ No ___

Commissioner Merrifield's Comments on SECY-06-0220, "Final Rule to Update 10 CFR PART 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (RIN AG24)"

I commend the staff on their efforts to enhance the Agency's effectiveness and efficiency in implementing the licensing and approval process for design certifications, standard design approvals, early site permits, combined licenses and manufacturing licenses. The staff has done an excellent job highlighting the rule changes, providing the basis supporting the changes, and documenting the resolution of the numerous public comments received. In voting on the final rule I have paid particular attention to the comments received, and the staff's proposed resolution to comments. I approve the publication of the final rule to amend the regulations contained in 10 CFR Part 52 subject to the following comments:

1. In Section 52.99(a), the staff has proposed that a licensee provide a detailed schedule for completion of all ITAAC for the staff to properly plan its inspections and verifications activities. Commentors have expressed concern about the staff expectation for the level of detail of the schedule as well as the timing of that submittal. The rule should be modified to account for licensees that do not immediately begin construction and the word "detailed" should be deleted from the rule text. The staff should continue to work with interested stakeholders to develop the specific guidance about the nature and content of the ITAAC schedule as part of its continuing infrastructure development activities.

2. I share a similar concern expressed by Commissioner Lyons that the use of the term "sufficient information" in section 52.99 does not provide the necessary clarity for the rule. I recommend that the word sufficient be deleted from sections 52.99 (c)(1) and (2) of the rule as currently proposed. I encourage the staff to meet with relevant stakeholders to establish the appropriate threshold for the minimum information requirements necessary for the staff to make the findings necessary under Section 52.103. I do not believe that the licensee must submit any more information than that which is necessary for the staff to make its reasonable assurance finding that the ITAAC has been performed and met. In reaching this conclusion I carefully reviewed the legislative history surrounding section 189(B) of the Atomic Energy Act. The focus of section 189(B) was to severely restrict the likelihood of a hearing on ITAAC such that hearings are limited to only those instances when an intervener can make a prima facie showing that one of the ITAAC have not been met. I do not believe that Congress, in attempting to limit hearings, intended to expand the information that licensees are required to submit in order to assist interveners in framing contentions. That being said, I do appreciate the concern of the staff that with less information on the docket any hearing held will become a review of the staff's inspection program. In that vein, additional discussion should be added to the statement of considerations regarding 52.99 to make it clear that it is the licensee's burden to demonstrate compliance with the ITAAC. The staff should revise the discussion on this issue at pages 52-53, 116, 118, and 359-360 to reflect this position.

3. I endorse the modifications made to the rule related to when the staff can use either an environmental impact statement or an environmental assessment to complete the necessary environmental evaluations for licensing. I also approve the modifications to the rule that establish finality to the agency environmental findings made during an early site permit review. I support the changes to the rule that establish a process that would require the licensee to take a hard look to see if there is new information since the earlier permit decision that would potentially affect the Commission's previous environmental findings. Equally important, the process contains an opportunity for members of the general public to identify to the

Commission new and significant information that could change the previous staff decisions made during an early site permit review. However, I believe that the opportunity for the public to participate in the environmental process should not wait until the staff has drafted its environmental findings. Therefore, the final rule should be revised to incorporate the use of a scoping process. The use of an early scoping process, as currently required for environmental impact statements, to seek early identification of new and significant environmental impacts would add additional regulatory predictability to the licensing process.

I believe that the rule language, which would allow an environmental assessment to be done for a COL when a full environmental impact statement had been completed at the ESP stage to be fully consistent with the goals and purposes of NEPA. The purpose of NEPA is to ensure that environmental values are considered in federal decision-making. The purpose of NEPA is not to redo work that has already been performed. This proposal to not redo work already performed at the ESP stage at the COL stage is also consistent with the Council on Environmental Quality's first principal of modernizing NEPA implementation, i.e., to ensure "timely and cost effective environmental reviews while maintaining environmentally sound decision-making." Completing a full EIS at the ESP stage followed by an EA at the COL stage with a check for new and significant information ensures that environmental issues are taken into account sooner rather then later. I further agree with the staff that there is no need to define the ESP and COL's as "connected actions." Pursuant to Council on Environmental Quality regulations a "connected action" is an action that (i) Automatically trigger other actions which may require environmental impact statements. (ii) Cannot or will not proceed unless other actions are taken previously or simultaneously. (iii) Are interdependent parts of a large action and depend on the larger action for their justification. See 40 C.F.R. 1508.25(a)(1). An ESP cannot be considered a connected action because it does not automatically trigger a COL, nor does it require a COL to proceed. Similarly, a COL cannot be considered a connected action to an ESP because it does not automatically trigger any other action or require an ESP. Either can proceed independently of the other.

4. I further agree with the requirement that operating experience be factored into the design certification reviews, however, I believe that the language in the draft final rule would be difficult to implement in its present form. I believe Section 52.79(a)(37) should be modified to read, "The information necessary to demonstrate how operating experience insights have been incorporated into the plant design." I appreciate the view of some industry commentators that it is the staff's responsibility to assure that the Standard Review Plan contains the necessary guidance relating to lessons-learned from operating experience, both domestic and foreign, but I do not find it persuasive. The industry has access to international operating experience through INPO's association with the World Association of Nuclear Operators (WANO) and distributes relevant international operating experience through its own internal reports.

5. I approve the staff addition of a design certification change process into the final rule at section 52.63(a) that would permit amendments of design certification rules to incorporate generic resolutions of design acceptance criteria, to correct errors, or increase standardization without meeting special backfit requirements. I am not persuaded by industry arguments that the adoption of this rule provision will potentially remove the finality attributed to design certification rules. I recommend that the staff expand the discussion in section V.C.7.g of the supplementary information to discuss the application of the rule provisions for increases to reliability or efficiency.

6. I agree that the docket date should be the implementation date for establishing the set of

regulatory requirements to be used for the review of an application. I further agree that the application should be evaluated against the set of acceptance criteria established in the staff Standard Review Plan. It is my view that a requirement for a licensee to address the spectrum of NRC guidance at the time of application is onerous and a substantive departure from previous staff practice without any commensurate benefit. I further conclude that grand-fathering pending early site permit application is not necessary.

7. The staff has modified the final rule to remove a requirement to submit for staff review a plant-specific probabilistic risk assessment. In support of the rule change, the staff argues that over the last several years, the NRC staff and other PRA experts have participated in an extensive effort that has resulted in a number of PRA standards applicable to new reactors. The ACRS provided its views that the complete PRA must be submitted for staff review and offered that if the complete PRA is not submitted, the review would have to be performed at the applicant's offices. At this particular time, I am not persuaded by the ACRS arguments, therefore, I support the staff proposed change to the rule to require the submittal of a summary description of the PRA and its results. As I understand the revised rule, a design-specific PRA is still required to meet the provisions of 52.47(a)(27) and a plant-specific PRA will still be required to meet the provisions of section 52.79(a)(46). However, the staff revision to the rule represents a change in focus of its review emphasis from checking all of the details of the PRA models and inputs to an approach that verifies that the PRA was developed using available standards, and focuses the overall staff review on those areas most important to public health and safety.

8. I have a number of comments that deal specifically with modifications to Part 2. For the reasons stated in my vote on COMSECY-06-0048, I remain concerned about the burden of mandatory hearings. Thus, I would alter the language of 2.104 to ensure that the Commission has maximum flexibility in the conduct of mandatory hearings. I would reduce the mandatory content of the notice of hearing to eliminate all references to findings made by the presiding officer. The only findings a presiding officer should make should be those regarding contested issues. The current rule text is somewhat vague as to whether or not the separation of functions rule applies to uncontested proceedings. I would amend the language of 2.348 and make explicit that this rule has no applicability to uncontested proceedings, or uncontested issues in contested proceedings.

9. The staff has amended section 2.340 to remove the automatic stay provision for Commission review. This Three Mile Island era provision was to ensure greater Commission involvement in licensing decisions; this need continues to exist today. That being said, I also acknowledge that there is little regulatory benefit to continue to impose this requirement by rule. Therefore, I support the staff modifications to section 2.340 to remove the requirements for a stay for Commission review. However, as a matter of policy, I expect that the staff will provide the Commission sufficient notice through a briefing with supporting documentation at least 10 days before the appropriate Office Director issues any license.

10. Currently we have a consistent numbering system throughout our regulations where deliberate misconduct is found in XX.5, employee protection is XX.7 and completeness and accuracy of information is XX.9. I note that in Part 52 this has been altered and the rule text has deliberate misconduct at 52.4, employee protection at 52.5, and completeness and accuracy of information at 52.6. It seems to me that it has been beneficial to have this

consistent and I question the wisdom of this departure. I would like the staff to consider whether the benefits of altering the numbering system outweighs the potential confusion that will result.

11. I encourage the staff to ensure that the document is internally consistent prior to publication of the final rule. For example, the requirement for a mandatory hearing for a manufacturing license has been eliminated, but there are still references in multiple places in the supplementary information to the findings that must be made by a presiding officer in an uncontested hearing on a manufacturing license (see page 297). Similarly, there are a few references to the appeal panel and the submission of views on antitrust aspects on a application (see pages 505 and 849).

12. I strongly agree with the removal of the mandatory hearing requirement for manufacturing licenses. In my view, this change from the proposed to the final rule is an example of how notice and comment rulemaking under the APA is supposed to work. Commenters recommended removing the mandatory hearing requirement because mandatory hearings are not the best way of resolving technical issues. The agency does not need a compelling reason to adopt a different policy than was initially proposed in the proposed rule. If the agency is offered a better option through notice and comment rulemaking, it should adopt it. In the instant case I can see no benefit to holding a hearing when no one has requested one. In no way does excluding a manufacturing license from the mandatory hearing requirement eliminate the opportunity for public comment. Any member of the public can seek a hearing on a manufacturing license, and such hearing will be granted if the standards set forth in 2.309 are met.

13. In a December 8, 2006 letter, NEI proposed a modification of the rule to incorporate the evaluation of beyond the design basis security events into Part 52 without the need to solicit additional comment and to eliminate any proposed rulemaking on section 73.62. While the NEI proposal may ultimately prove to be an elegant solution, a full evaluation of the NEI proposal at this time would require additional delay to the promulgation of the final rule for Part 52. Therefore, I support moving forward with the final rule at this time and I will have additional comment on the NEI proposal as part of my vote on the proposed rule for security assessments (section 73.62) and the associated SECY-06-0204.

14. I recommend that the staff make all the necessary conforming changes to the supplementary information and the rule before publication of the final rule. The changes should include any necessary discussion and documentation of the resolution of comments received after the close of the comment period as part of the final rule package.

Finally, as one of the proponents of the limited work authority proposed rule, I agree with the comments provided by Chairman Klein related to the changes in the definition of construction and the time a limited work authority application can be submitted.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: **COMMISSIONER JACZKO**

SUBJECT: **SECY-06-0220 - FINAL RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS" (RIN AG24)**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below___ Attached X None ___

SIGNATURE

11/3/09

DATE

Entered on "STARS" Yes ___ No ___

Commissioner Jaczko's Comments on SECY-06-0220
Final Rule to Update 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"

I approve in part and disapprove in part of the draft final rule for Part 52. I approved of the proposed rule on Part 52 because I believed then, and continue to believe now, that in large measure the proposed changes were aimed at clarifying current Part 52 and that such clarification would be useful. I continue to approve of the clarifying changes to Part 52.

Unfortunately, however, the draft final rule has gone far beyond refining current Part 52 and instead includes many substantive changes to the regulatory provisions. I do not believe the agency should finalize these significant changes without first seeking public comment. Because additional comments can not be accomplished while maintaining the Commission's promise to Congress to finalize this rule before year's end, I can not support these new provisions of the draft final rule.

Additionally, I have reviewed several late filed stakeholder comments. As discussed below, I agree with some of those comments. In addition, unless specifically noted below I concur with the staff's response to the comments provided by the Nuclear Energy Institute in its December 1, 2006 letter. Where appropriate, these staff comments should be incorporated into the federal register notice as part of the resolution of comments.

Changes to Section 2.340

First, I do not support the revisions to section 2.340 which address matters relating to the presiding officer's initial decision and its effect. As the Statement of Consideration makes clear, these changes are extremely broad and some of them have no connection to the part 52 rulemaking effort.

Moreover, some of the proposed revisions to section 2.340 are intended to remove the regulatory requirement for direct Commission involvement in all production or utilization proceedings. The explanation for this change, which places a noticeable emphasis on "streamlining" the agency's processes, acknowledges that removing the "automatic stay" provisions pending Commission review of initial decisions will limit the Commission's involvement, but contends that it will "not compromise the Commission's commitment to the protection of public health and safety or to a fair hearing process".

I am, however, unconvinced by this statement. The Commission has never tested the new part 52 licensing process. To immediately delegate this responsibility to the staff with no experience using the process is an abdication of the Commission's responsibility to provide reasonable assurance of public health and safety. After some experience with licensing proceedings, the Commission could consider modifying this process. The Commission is ultimately responsible for all licensing decisions and the process for decision-making should transparently reflect this obligation. Some comments received by the Commission express concern with the changes to this provision, viewing the changes as an abandonment of NRC's accountability. I believe that the Commission should not depart from our previously adopted practice, and that we certainly should not do so without consulting the public.

Moreover, to remove the automatic stay provision places the Commission in the awkward position of having to hold up the issuance of a license if there are any issues to which the Commission may want to speak - regardless of whether the issues involve safety-related items.

Maintaining the automatic stay provision pending Commission review is not an impediment to the efficient issuance of a license, but in practice could mean the opposite.

I understand that, legally, the agency can make "procedural" changes to the regulations without first seeking public comment, but whether the agency can and whether the agency should are two different questions and I believe the answer to the latter is "no". Several years ago, when the Commission decided to revise Part 2 of the agency's regulations, the Commission did choose to seek public comment and received, by final rule count, almost 1500 responses. The fundamental importance of public participation in the adjudicatory process is not limited to participation in hearings, but also to participation in the processes that control the adjudications. I agree with the Commission's statement in the final Part 2 rule, quoting from a 1975 adjudicatory decision, that "[p]ublic participation ...is a vital ingredient to the open and full consideration of licensing issues and in establishing public confidence in the sound discharge of the important duties which have been entrusted to us." 69 Fed. Reg. 2182 (citation omitted).

Appendix Q

Regarding appendix Q of Part 52, which addresses early staff review of site suitability issues with respect to a specific site, I continue to support the position expressed in the proposed rule of removing this appendix and do not support the draft final rule's change of position. Apparently, based upon comments and in an attempt to allow ESP and COL applicants "maximum flexibility" in seeking early reviews of issues, this appendix was instead retained. I see no benefit to an appendix that simply makes more work for the NRC staff with no real safety or environmental benefit to justify this waste of resources. If applicants want to have site suitability issues addressed, the applicants should file an ESP. If applicants are not willing to invest their time and resources in using part 52 as originally envisioned, I see little value in having the staff prepare additional reports which are not even binding on the Commission or the presiding officer in any hearing.

Construction Permit – Ability to Reference ESP and Certified Design

I do not agree with the provision allowing a part 50 applicant to attempt to use portions of the part 52 process, such as the benefits provided by referencing an ESP or certified design. Thus, I do not believe staff should invest resources in developing regulatory guides or standard review plans in the event that an applicant should request this. The parts 50 and 52 processes are distinct in many ways and an applicant should not be able to pick and choose the pieces of the process they like best, nor is it in the interest of the agency to encourage such behavior. Instead, the draft final rule language should make clear that the agency establishes processes for a reason and that the agency expects those processes to be followed.

Programmatic ITAAC

After a multi-year discussion and debate about whether or not ITAAC were required for operational programs, the Commission decided that a COL applicant was not required to have ITAAC for operational programs so long as the applicant fully described the operational program and its implementation in the combined license application. I expressed concerns with that view at that time. And given some of the discussion surrounding this issue in this rulemaking, I can not help but have continuing concerns about how some of these operational programs can be "fully described" in the COL, especially since there appears to be some misunderstanding over the preliminary question of which programs need to be "fully described". The staff sought comment on whether there were any additional operational programs that needed to be identified in this rulemaking and surprisingly, despite the detailed review of the

proposed rule provided by many commenters, it appears that commenters failed to identify some of the operational programs inadvertently missing from the proposed rule's list. Fortunately, the staff, upon further review on its own initiative, found almost a half-dozen such programs inadvertently excluded and is now adding those programs to the draft final rule. For the sake of clarity if and when the agency receives a COL application, I hope that the list is now truly exhaustive.

Environmental Finality

I also disapprove of some of the NEPA related changes in the draft final rule. I join with Commissioner Lyons in disapproving of the change allowing preparation of an environmental assessment with a finding of no new and significant information for a COL application referencing an ESP. This change appears to be primarily based upon stakeholder comments which were not supportive of the proposed rule language treating both the ESP and COL as major federal actions and thus both requiring an EIS. Although the staff is seemingly unwilling to delve into the murky legal waters regarding whether or not the ESP and COL can be considered "connected actions" under NEPA as some commenters suggest, the NEPA process outlined in the draft final rule essentially does in practice what the staff was unwilling to do in words.

Moreover, I think the process outlined in the draft final rule, at a minimum, violates the spirit of NEPA. I find the argument presented by some of the NRC staff members who disagree with this change very persuasive. I, too, find it difficult to understand how a potential 100-year project such as the construction and operation of a nuclear power plant could go forward without its own environmental impact statement. The proposed rule language explained, "[t]he NRC's regulations and the applicable case law interpreting the National Environment Policy Act of 1969 (NEPA), as amended, support the staff's belief that, inasmuch as an ESP and a COL are major Federal actions significantly affecting the quality of the human environment, both actions require the preparation of an EIS." I continue to support this position and see no compelling arguments presented that would encourage me to support this dramatic change of position in the final rule.

I also want to add that I am encouraged by the process the staff used to present the different views on this issue. I also commend the management who, while perhaps not agreeing, recognized the value in presenting the arguments both to the Commission and to the stakeholders by addressing this disagreement in the public SECY paper.

Updating Probabilistic Risk Assessments (PRAs)

I disagree with the proposed changes to the PRA requirements in the draft final rule. As I indicated during the November 9, 2006, public meeting on Part 52, I believe having a living PRA is fundamental for moving towards a more risk informed regulatory process. Therefore, I believe the final part 52 should ensure periodic PRA updates over the lifetime of a plant.

Additionally, I do not approve of the changes regarding the design-specific PRA. The proposed rule, in section 52.47(b)(1) would have required design certification applicants to submit a design-specific PRA. The draft final rule, however, added a new section 52.47(a)(27) which would allow the submission of only a description of the design-specific PRA and its results in the Final Safety Analysis Report, rather than submission of the PRA itself. As the ACRS explained, to certify a design or approve a COL, a detailed review of the PRA is necessary. While there are arguments that an auditing approach would be sufficient, I believe it is both less burdensome and more efficient for the staff to have all the information it needs for review at its

disposal rather than relying upon information to be supplied subsequently via audits or requests for additional information (RAIs). The applicants must have a PRA. Thus, submission of an existing PRA does not appear to place any undue burden on an applicant, yet having to audit or RAI information regarding the PRA seems to place undue burden on the staff. Thus, I continue to support the language in the proposed Part 52 rather than the changes made in the draft final version.

Mandatory Hearing for Manufacturing Licenses

I am not convinced by the arguments presented against adopting a requirement for a mandatory hearing in connection with the issuance of a manufacturing license. The argument is premised upon the idea that adjudicatory hearings are perhaps not the best place to resolve technical design issues and the example provided is that of a certified design. A certified design, however, is afforded public comment in the rulemaking process. A manufacturing license by contrast is guaranteed no similar public venue. Thus, I see no compelling basis to exclude a manufacturing license from the mandatory hearing requirement.

Finality of Early Site Determinations - Emergency Preparedness

I do not approve of the provisions in the final rule which allow finality for changes made to emergency plans submitted as part of an ESP as long as the changes do not result in a decrease in effectiveness. The argument is that, because current reactor licensees can make these sorts of changes to emergency plans - changes that do not result in a decrease in effectiveness - without seeking NRC approval, then the agency should afford the same right to those with an emergency plan included in the ESP and such changes should not impact the finality of the emergency plan. I disapprove of this provision because I believe a change in an emergency plan at an operating reactor, where emergency plans are tested every two years, is inherently different than a change to a theoretical emergency plan that has never been practiced at the proposed location. If an emergency plan included in an ESP is in use at a co-located operating reactor, that logic holds and to this extent, I approve of the final rule. But the same does not hold true for emergency plans in use by operating reactors in a different location than the location proposed in the ESP, or for emergency plans that are not in use by any existing reactor. ESPs and emergency plans are, by their very natures, site-specific. Thus, a change to the emergency plan that may not result in a decrease in effectiveness in one location could readily create a decrease in effectiveness in a different location. Additionally, there are many external factors (infrastructure, hazards, federal state and local emergency preparedness systems) that could change during the 20-year validity of an ESP that would require revisiting the emergency plan prior to its implementation. Therefore, for every circumstance except that of an emergency plan currently in use at a reactor co-located with the site of the relevant ESP, any changes made to the emergency - regardless of whether or not they are expected to result in a decrease in effectiveness - should not be given finality.

International Operating Experience

Regarding, international operating experience, I agree with the resolution suggested in Commissioner Lyons' vote. This debate is not about whether appropriate international operating experience is addressed, but is about who decides what international operating experience is necessary to be addressed. I understand that the NRC receives information regarding international operating experience from the International Nuclear Event Scale (INES) and the Web-based Incident Reporting System (WBIRS). According to the staff, this information is collected, screened, evaluated and applied using the same processes which are used for

domestic operating experience. Thus, theoretically, the words "international operating experience" could be removed because international operating experience should already be covered by some sort of NRC generic communication. The staff's screening of international operating experience, however, is only performed to determine if information has applicability to the current fleet of operating reactors. Because future applications may reference new designs that do not have applicability for the current fleet of reactors, the Commission should separately direct the staff to ensure that the operating experience branch begins screening international operating information that would be relevant for new designs under review.

Therefore, I agree with Commissioner Lyons that the language in 52.47(a)(22) should be modified to delete the reference to "international operating experience" and additional direction should be provided to the staff to ensure that the operating experience branch is assessing the appropriate international events.

Sufficient Information to Demonstrate Acceptance Criteria Have Been or Will Be Met

I support OGC's determination that "sufficient information" should be provided by applicants to support the licensee's conclusion that the acceptance criteria have been or will be met. The regulatory requirements must give practical effect and meaning to Congress' intent. I agree that the statutory intent was to create a high burden for the hearing regarding ITAAC and that the information to be provided is limited to the specifics of the ITAAC itself. But it appears to me that without any applicant information explaining how the ITAAC were satisfied, a prima facie case would be much easier to demonstrate. Thus, OGC's interpretation is the closest to accomplishing statutory intent and the language, "sufficient information" should, therefore, be retained.

1/5/07

Gregory B. Jaczko Date

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER LYONS

SUBJECT: **SECY-06-0220 - FINAL RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS" (RIN AG24)**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below___ Attached X None ___

Peter Lyons
SIGNATURE

12/15/06
DATE

Entered on "STARS" Yes X No ___

Commissioner Lyons' Comments on SECY-06-0220

I approve for publication in the *Federal Register* final amendments to Title 10, Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," which would also retitle 10 CFR Part 52 and make conforming changes to related sections of the regulations in Title 10, Chapter 1. I also approve certifying that this rule will not have a significant economic impact on a substantial number of small entities in order to satisfy the Regulatory Flexibility Act.

I think the staff did an exceptional job in drafting this document and in presenting it to the Commission in an expeditious manner. I believe that the careful updating of Part 52 and related regulations will enhance the submission and review of ESP, Design Certification, and COL applications and will result in more efficient and predictable regulatory processes.

I have a number of specific comments to make regarding the rule. Some of my comments touch upon matters raised by the Nuclear Energy Institute in their December 1, 2006 letter, commenting on the draft final rule. I have also attached edits to the final rule language and the related statements of consideration.

My first observation is that in the proposed rule, the staff would have had to prepare an environmental impact statement with respect to all COL applications, regardless of whether they reference an ESP. In the final rule, the staff will prepare an environmental assessment for a COL application referencing an ESP if the EIS for the ESP discloses benefits and costs of the proposed actions and all environmental issues and there is no new and significant information identified related to matters resolved in the ESP proceeding. New and significant information may be addressed as a supplement to the ESP EIS in connection with the COL application or in a COL EIS, which may otherwise incorporate by reference the ESP EIS.

I believe that the best approach would be for the staff to prepare an EIS for all COLs. As the SOC for the final rule states:

> The NRC's regulations and the applicable case law interpreting [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.

See p. 282 (emphasis added). *See also* 10 CFR § 51.20(a)(1). This is consistent with the environmental review process set forth in the proposed rule.

It seems that any benefit of dispensing with the EIS at the COL stage would be offset by the risk of not conducting an EIS. One benefit seems to be the elimination of performing an EIS at the COL stage, and all that entails. However, in preparing an EIS for the COL, the staff need not necessarily redo its EIS analyses for the ESP but can incorporate the ESP EIS by reference in the COL EIS. The SOC for the rule recognizes:

> . . . . [T]he NRC staff intends to incorporate the early site permit EIS by reference in the combined license EIS.

See p. 283. I further note that NEI recommends a scoping-like process to be used for the consideration of environmental issues at the COL stage that had not been resolved at the ESP stage. If a scoping-like process is employed, as suggested by NEI, there is even less efficiency to be gained in proceeding with an EA rather than an EIS at the COL stage.

Finality would not be impacted in conducting two EISs. Information and issues may be considered resolved in the EIS for the COL that are set forth in the EIS for the ESP, unless the scoping process identifies new and significant information. This is consistent with NEPA law since all relevant issues will be considered at least by the time a COL issues. As the United States Court of Appeals for the 7th Circuit recently stated, "Courts have permitted agencies to defer certain issues in an EIS for a multistage project when detailed useful information on a given topic is not 'meaningfully possible' to obtain, and the unavailable information is not essential to determination at the earlier stage." *See Environmental Law and Policy Center v. United States Nuclear Regulatory Commission and Exelon Generating Co.*, (7th Cir.,December 5, 2006), slip op. at 14.

Second, COL applicants referencing an ESP must include any new and significant information for issues related to the impacts of construction and operation of the facility different from the ESP stage. The term "new" in the phrase "new and significant information" means not considered in preparing the ESP environmental report or EIS and not generally known or publicly available during the preparation of the EIS. The term "significant" means "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. *See* p. 284. I agree with NEI that what is meant by "new and significant" in this context is vague and could lead to confusion. For example, it seems that the standard for significance: whether a mater may "potentially affect" an NRC finding constitutes an unreasonably low threshold. If an EIS is to be prepared for the COL, the scoping process for that EIS could be used to define what issues should be reconsidered that were not addressed in the EIS for the ESP.

Third, with respect to design certification amendments, the rule allows amendments of certification information provided the amendment will be applied to all plants that reference the design certification rule. NRC will give special consideration to comments from applicants or licensees who reference the design certification rule regarding whether they want to backfit their plants with these additional design changes. *See* p. 341. The rule should make it clear that such amendments will not be imposed if it is impossible or impracticable for a plant that has already applied for a license or permit to make the necessary changes unless adequate protection is impacted. In addition, the SOC should indicate that the phrase "special consideration" does not mean that an applicant or licensee is able to veto the imposition of a requirement with respect to its facility.

Fourth, with respect to design certification rule changes, I agree that for the sake of clarity, the SOC should state that the phrase "certification information" as used in 52.63 is to distinguish the language in the DCRs from the information (Tier 1 and Tier 2) incorporated by reference in the DCRs. Also for the sake of clarity, the SOC should discuss how, with respect to 52.63(a)(1)(vi), changes to incorporate alternative design information may be considered as contributing to increased standardization such that they can be implemented through the rulemaking process.

Fifth, the final rule states that within 10 days of the issuance of a presiding officer's initial decision, the Director of NRR or NRO in a contested proceeding shall issue the license or permit within 10 days notwithstanding the pendency of a motion for stay under 10 CFR 2.342. I would prefer the language clearly state that such stays will not be entertained. *See* p. 231.

Sixth, page 52 contains the statement that "[i]n 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." Licensees, however, will be required to submit a schedule, and therefore, schedules may not necessarily be exempted from FOIA disclosure. This statement should therefore be clarified.

Seventh, new section 52.39(c) states that intervenors in proceedings for applications that reference

an early site permit may raise contentions to litigate the issue of whether "[a] variance requested . . . is unwarranted or should be modified." 52.39 (c)(iii). It seems to me that as with other potential contentions, a contention pertaining to a variance should demonstrate a substantial underlying safety concern or material safety issue.

Eighth, with respect to certified designs, the proposed rule includes a requirement that the applicant address comparable international operating experience. The language for 10 CFR § 52.47(a)(22) states that an applicant should address "how insights from relevant international operating experience have been incorporated into the plant design." *See* p. 333. Reactor designers and vendors bear responsibility for considering relevant and recent operating experience that is not likely to have been assimilated into the NRC regulatory framework, in particular that which may have revealed design errors or weaknesses. Therefore, I believe that the burden to ensure relevant and recent operating experience is considered falls to both the applicant and the staff, with the staff providing an independent perspective. I understand that the staff operating experience program gathers, assesses, and disseminates operating experience, both internally and externally as appropriate, to various customers including technical branches conducting new reactor licensing reviews and those responsible for updating regulatory requirements and guidance. The current proposed language should be replaced with:

> "The information regarding how relevant and recent operating experience insights have been considered in the plant design."

and the following direction to staff should be included in the SRM:

> "Staff should ensure the scope of the NRC Reactor Operating Experience Program includes international operating experience that is relevant to designs under review by the staff or under construction in the U.S."

Ninth, section 52.99(c)(1) states that licensees shall notify the NRC that inspections, tests, or analyses of ITAAC have been successfully completed and acceptance criteria have been met. The notification must contain "sufficient information" to demonstrate that this has been done. In its December 1, 2006 letter, NEI states that the term "sufficient information" is vague and impractical. I believe that the term "sufficient information" could be tightened to require "a summary description of the bases for the licensee's conclusion that the inspections, tests, or analyses have been performed and that the prescribed acceptance criteria have been met." Similar language should be provided in 10 CFR § 52.99(c)(2) for uncompleted ITAAC. I recognize that guidance will be forthcoming as to what should be included in the information to be provided to show ITAAC completion.

Tenth, the language in section 52.99 should more closely follow the language of section 185b. of the AEA. Thus, 52.99(b) should be revised to read, "any one of the prescribed acceptance criteria have been met." Also, 52.99(c) should be revised to read, "the prescribed inspections, tests and analyses have been performed and that the prescribed acceptance criteria have been met."

Eleventh, the requirement in 52.99(a) should allow a licensee to submit its ITAAC schedule "no later than the start of construction as defined in 10 CFR 50.10(b)" rather than one year after the COL is issued. This would account for those licensees that delay construction in order to clear the site or engage in other activities after the COL issues.

Twelfth, section 10 CFR 52.47(a)(23) and 52.79(a)(38) should either identify the severe accidents for which an evaluation is required or delete the parenthetical information and instead describe what severe accident attributes are meant to be captured by the requirement.

Thirteenth, I believe that the regulations should specify that ESP applications received prior to the date of the rule are to comply with the application content and approval requirements in effect at the time they were submitted.

Fourteenth, the draft rule requires that the facility be evaluated against "NRC's application and review guidance" instead of the SRP alone. *See* 52.17(a)(xii), 52.47(a)(9) and 52.79(a)(41). As NEI points out in its letter, the change alters NRC practice of evaluating against the SRP. The staff should delete this requirement and include a discussion about the importance of applicants' use of application guidance in the SOC. The staff should also include in the SOC a discussion of how plants using the design centered approach could address the requirement.

Fifteenth, I agree with the industry, the staff, and the ACRS that the regulations do not need to require licensee PRA updates to be submitted to the staff. I also agree with the staff that a licensee's PRA maintenance and update program may be described in documents such as the FSAR. However, including in the regulations the requirement that PRAs be periodically updated would simply codify what is already expected to occur and would emphasize the importance the Commission gives to maintaining and utilizing plant-specific risk insights in plant operations, maintenance, and modifications. Therefore, staff should include a requirement that COL licensees periodically review and update, as required, their PRA to ensure it continues to reasonably reflect the as-built as-operated plant. The specific periodicity should be described elsewhere.

Sixteenth, notwithstanding the ACRS recommendation to the contrary, I am not persuaded that we must continue to require an applicant to submit its entire PRA documentation, model, and operating code to the NRC as part of its application. Specific information needed by the staff or ACRS to fulfill their responsibilities is always available from the applicant. Reviews of PRA models should be linked to safety questions. Rather than expend substantial efforts in reviewing a PRA for which there are no regulatory requirements for the specific technical assumptions used, staff and ACRS should focus their initial PRA reviews in areas needed to better understand the safety margins or defense-in-depth bases. Therefore, I agree with the staff's approach to require a description of the PRA in the applications.

Peter B. Lyons 12/15/06

Peter B. Lyons Date

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

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.

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 this 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.

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

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

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

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[3]This 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

Replacement

for pages 76 and 308:

A definition of *modular design* is added to ~~explain the type of modular reactor design to which~~ make clear the Commission's intend~~ed~~t ~~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~~ multiple separate ~~nuclear~~ reactors modules ~~in a single power block~~ with a single shared power conversion system, or multiple separate reactor modules each with their own power conversion system but having shared support systems (similar to previously licensed multi-reactor sites).

During the period that ~~the power block is~~ multiple separate reactor modules are under construction at a site, the Commission could separately authorize operation for each ~~nuclear~~ reactor module when ~~each reactor and~~ the module 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~~ of "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.~~

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

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

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 (SAMDAs) 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.

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.

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.

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

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

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

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.

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 (e), 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 2.764[6]) 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

[6]31 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

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

design certification regulation. Each of the environmental assessments and FONSIs 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

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 of 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

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.

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 represent 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

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

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.

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~~ possible arrangements of modules and site. Modular ~~nuclear power plant~~ designs are defined in § 52.1. Modular plant designs utilize ~~are not portions of a single nuclear plant; rather they are separate nuclear power~~ multiple reactors with some shared or common systems, including the possibility of a shared power conversion system.

§ 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

§ 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, 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

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 statuary 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 by 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.

§ 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

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

[14]Subpart 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 and 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.

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[15]Subpart 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 the common FSAR; the information from the referenced FSAR must be included within each application's FSAR.

Section 4

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 or 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

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

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~~ (1) possible operating configuration of the plant and site, including variations in, or and analyze

reactor modules

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.

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.

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§ 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.

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

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.

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.

(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;