[7590-01-P]

NUCLEAR REGULATORY COMMISSION
10 CFR Part 70
RIN 3150 - AF22

Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the domestic licensing of special nuclear material (SNM) for licensees authorized to possess a critical mass of SNM, that are engaged in one of the following activities: enriched uranium processing; fabrication of uranium fuel or fuel assemblies; uranium enrichment (other than existing gaseous diffusion plants certified under 10 CFR Part 76); enriched uranium hexafluoride conversion; plutonium processing; fabrication of mixed-oxide fuel or fuel assemblies; scrap recovery of SNM; or any other activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety or the environment. The amendments establish performance requirements, require affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety necessary to prevent these potential accidents and/or mitigate their consequences; require the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; require the safety bases to be maintained, and changes reported to NRC; allow for licensees to make certain

changes to their safety program and facilities without prior NRC approval; require reporting of certain events; and require the NRC to perform a backfit analysis under specified circumstances.

EFFECTIVE DATE: The final rule, with the exception of § 70.76, is effective (Insert 30 days after publication of this final rule). Section 70.76 will become effective after the issuance of staff guidance for the implementation of that provision. Once such guidance has been developed, the NRC will publish a Federal Register notice specifying the effective date of § 70.76.

FOR FURTHER INFORMATION CONTACT: Theodore S. Sherr, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7218; e-mail tss@nrc.gov, Heather Astwood, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-5819; e-mail hma@nrc.gov, or Andrew Persinko, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6522; e-mail axp1@nrc.gov.

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I. Background

On July 30, 1999 (64 FR 41338), the Commission published a proposed rule for public comment that would amend its regulations governing the domestic licensing of SNM for certain licensees authorized to possess a critical mass of SNM. The Commission's action was in response to a Petition for Rulemaking, (PRM)-70-7, submitted by the Nuclear Energy Institute (NEI), which was published on November 26, 1996 (61 FR 60057). The proposed rule was intended to grant the NEI PRM in part and would modify the petitioner's proposal. The majority of the proposed modifications to Part 70 were included in a proposed new Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." These modifications were proposed in order to increase confidence in the margin of safety at the facilities affected by the rule.

In developing the proposed rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach that included: (1) the identification of performance requirements for prevention of accidents or mitigation of their consequences; (2) the performance of an ISA to identify potential accidents at the facility and the items relied on for safety; (3) the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; (4) the maintenance of the safety bases, including the reporting of changes to the NRC; and (5) the allowance for licensees to make certain changes to their safety program and facilities without prior NRC approval.

The 75-day public comment period on the proposed rule ended on October 13, 1999. During and after the public comment period, the NRC staff posted on the NRC web site revised versions of the draft Standard Review Plan (SRP) that would implement the proposed requirements (i.e., on August 4, 1999, a complete draft SRP was posted, and revised chapters, taking into account comments received, were posted during the period March 16 - April 3, 2000). In addition, three stakeholder meetings were held to discuss the SRP (September 14-15, 1999, February 9, 2000, and April 18-19, 2000).

II. Public Comments on Proposed Rule

In preparing the final rule, the NRC staff carefully reviewed and considered more than 90 comments on the rule, included in 9 individual letters filed during the public comment period. In addition, 13 submittals containing more than 200 specific comments were received on the SRP. To simplify the analysis, the NRC staff grouped all written comments on the rule into the following major topic areas: Performance Requirements and Design Criteria; Content of Applications and ISA Summary; Safety Program; Change Process, License Renewal and Backfit; Definitions; and Miscellaneous. A more detailed analysis is also documented as an attachment to SECY-00-0111. A review of the comments and NRC staff's responses follow:

A. Performance Requirements and Design Criteria

Comment A.1: One commenter stated that the proposed rule should specify dose limits for anticipated occurrences similar to those in §§ 72.104 and 72.106. This part of the rule would then cover the range of likelihood (anticipated, likely, unlikely, and highly unlikely) of potential accidents that could occur at nuclear fuel cycle facilities. This could result in an increase in the number of structures, systems, and components (SSCs) relied on for safety and would impact the design, operation, and licensing of the mixed-oxide (MOX) facility.

Response: No change in the rule language has been made. The dose limits for normal operation are contained in 10 CFR Part 20 [viz., 0.05 Sv (5 rem) Total Effective Dose Equivalent (TEDE)/yr for a trained worker]. The NRC staff views "anticipated occurrences" to be conditions of normal operations, and believes that the measures currently used by Part 70 licensees to comply with Part 20 have been and will continue to be successful in protecting workers and the public during normal operations. Thus, there is insufficient justification to require identification of ‘items’ to demonstrate compliance with Part 20 during normal operations.

Comment A.2: One commenter proposed that the NRC maintain consistency with past precedent (i.e., the Commission’s rationale in Part 60) and eliminate the specific worker dose limits in Part 70.

Response: No change in rule language has been made. The regulatory experience and industry events that initiated the effort to add a systematic accident analysis to Part 70 primarily involved health impacts to workers as opposed to the public. The NRC staff believes that the rule’s focus on both the potential impacts on workers and the public is appropriate. Based on the discussions and correspondence with the industry and public during development of the proposed rule, and all other comments on the proposed rule, there appears to be general consensus on this approach.

Comment A.3: One commenter stated, in response to the Federal Register notice request for comments on the clarity and effectiveness of the language used (per June 1, 1998, Presidential Memorandum), that the language in § 70.61(b) and (c) could be substantially clearer; the commenter provided an alternative plain language version of this section.

Response: The language in the proposed rule was written in response to public comments to focus on risk (i.e., likelihood times consequence) of accidents. The language has been changed, in response to the comment, to provide additional clarity. The proposed revisions provided by the commenter, however, are not merely editorial but represent substantive changes. They appear to have eliminated the concept of limiting risk, and instead, focused on the likelihood of accidents. The revised language in the rule attempts to retain the emphasis on controlling accident risks within appropriate performance requirements.

Comment A.4: Three commenters expressed concerns about how the worker dose limits in § 70.61(f) would be applied to “co-located workers.” One commenter suggested that the performance requirements in § 70.61 consider the individuals working in the nearby facilities as public when performing an accident analysis to determine the consequences of the accidents that may occur at the facility. The commenter concluded that this would result in a more stringent application of safety requirements for the protection of workers (e.g., additional items relied on for safety) at the MOX Fuel Fabrication Facility, Pit Disassembly, Conversion Facility, Immobilization Facility, and any other nearby DOE facilities, and would also have a substantial impact on the cost of the MOX facility. A second commenter agreed with this assessment, noting that a worker (as defined in § 70.4) who leaves the controlled area to perform a work-related function would have to be treated as a member of the public when performing an ISA and would be subject to the more stringent public radiation exposure limits. Outside of the controlled area the TEDE limit of 1 mSv (0.1 rem) for members of the public would apply [cf. 10 CFR 20.1301(a)(1)] rather than the annual TEDE occupational dose limit of 50 mSv (5 rems) (10 CFR 20.1201). According to this commenter, this problem has already arisen at the Hanford Tank Waste Remediation System where co-located workers are governed by the appreciably lower public dose limits. A third commenter agreed with the above positions and also stated that the NRC intends to consider individuals outside of the controlled boundary as workers if they are subject to Part 20 requirements. The commenter noted, as did the first commenter, that DOE requirements in 10 CFR Part 835 provide an equivalent level of protection, such that co-located workers -- who are subject to the requirements of *either* Part 20 or 10 CFR Part 835 -- should be considered “workers,” provided the licensee can demonstrate the ability to provide management measures (e.g., notification, evacuation, etc.) in the event of an emergency.

Response: NRC regulations do not specifically address personnel designated as “co-located” workers. In response to the comments, the first sentence in § 70.61(f) was changed to read as follows: “Each licensee must establish a controlled area, as defined in § 20.1003. In addition, the licensee must retain the authority to exclude or remove personnel and property from the area.” The licensee can set the controlled area at any location around its facility as long as it maintains control of that area as specified in Part 20 and retains the authority to exclude or remove personnel and property from the area. If the controlled area included the nearby Department of Energy (DOE) facilities, then NRC would consider the personnel working at those facilities to be “workers” for the purposes of the performance requirements of § 70.61, provided the conditions of § 70.61(f)(2) are met. The DOE and its contractors could satisfy these conditions by documenting their compliance with the requirements of 10 CFR 19.12(a)(1)-(5). To emphasize that the § 70.61(f)(2) requirements, regarding 10 CFR Part 19 training, can be satisfied in combination with existing training, rather than separate training solely devoted to 10 CFR Part 19, 10 CFR 70(f)(2) has been changed to read: “Provides training that satisfies
10 CFR 19.12(a)(1)-(5)”. To emphasize that the training provided to satisfy § 70.61(f)(2) requirements includes making individuals aware of the risks associated with accidents involving the licensed activities as determined by the ISA, the word “to” was changed to “and,” so that it now reads “to these individuals and ensures that they are aware of the risks associated with accidents”.

Regarding the concern about the worker who leaves the controlled area, the risk levels of § 70.61 for the public pertain to any individual, including workers, outside the controlled area. On the other hand, with respect to the applicability of the Part 20 occupational dose limit of

0.05 Sv (5 rem)/yr TEDE, a worker can receive an occupational dose and be subject to the Part 20 occupational limit, regardless of his location -- including activities outside the controlled area. The “assigned duties performed in the course of employment” is the distinguishing factor for radiation workers consistent with the definition of “occupational exposure” in 10 CFR 20. The changes to Part 70, including the “worker” definition, do not affect this. In this comment, the relationship between Part 20 annual limits for radiation exposure and the § 70.61 standards for a forward-looking severe accident assessment have been misinterpreted. Part 70 revisions do not limit doses outside a controlled area to 1 mSv (0.1) rem/yr.

Comment A.5: One commenter recommended that baseline criterion (8) be rewritten as follows: “*the design of items relied on for safety must provide for adequate inspection, testing, and maintenance, or adequate training, testing and qualification for personnel whose activities are relied on for safety, to ensure their availability and reliability to perform their function when needed.*”

Response: No change in rule language has been made. The baseline design criteria are applied from the outset of new design work and are primarily focused on physical design and facility features. The intent is to achieve a conservatively designed facility tolerant of both upsets and human errors. Adequate training, testing, and qualification, as noted in the comment, will be required as management measures under § 70.62, but the NRC does not see a need for the facility physical *design* to incorporate such training, testing, and qualification of personnel.

Comment A.6: One commenter stated that the baseline criterion on environmental and dynamic effects [§ 70.64a(4)] is unclear. For example, the commenter questioned if a formal Equipment Environmental Qualification Program, similar to that required under 10 CFR 50.49 and Regulatory Guide 1.89. According to the commenter, the NRC should clarify this requirement and should not impose requirements that may not be appropriate or necessary because of the nature of the processes at non-reactor nuclear facilities.

Response: No change in rule language has been made. The baseline design criterion on environmental and dynamic effects does not require a formal Equipment Environmental Qualification Program, similar to that required under 10 CFR 50.49 and Regulatory Guide 1.89. This criterion applies only to new facilities and new processes and is intended to ensure that potential ambient conditions are considered during the design of the facility.

Comment A.7: Two commenters had concerns regarding the defense-in-depth definition in § 70.64. One commenter stated that the definition does not reflect the defense-in-depth design philosophy as defined in WASH-1250, "The Safety of Power Reactor and Related facilities," which outlined three levels of safety concepts in the design of a nuclear facility. According to the commenter, the definition presented in §§ 70.64(b)(1) and (2) oversimplifies and does not adequately represent the implementation of the defense-in-depth philosophy in the design. In particular, the commenter noted that the preference for engineered controls over administrative controls and features that reduce challenges to items relied on for safety are only partially implemented in the concept [of defense-in-depth]. Another commenter agreed, stating that § 70.64(b)(1) appeared unnecessarily prescriptive by discouraging a licensee from using anything but an engineered safety control. According to this commenter, as long as the licensee can satisfactorily demonstrate that an administrative safety control or a system of administrative and engineered controls will enable the performance criteria to be satisfied, the choice of items relied on for safety and the nature of 'defense-in-depth' practices that is applied should be flexible. The commenter's view is that this flexibility, in the grading of defense-in-depth safety concepts, would be consistent with the ability granted a licensee to grade all aspects of its safety program [cf. § 70.62(a)].

Response: With respect to the footnote to § 70.64(b) that describes defense-in-depth, which applies to new facilities and new processes at existing facilities, the NRC staff believes that it does reflect the defense-in-depth design philosophy as defined in WASH-1250. Further, it reflects the Commission's current guidance on the relationship between defense-in-depth and risk-informed regulation that is discussed in the Commission policy white paper, "Risk-Informed and Performance-Based Regulation." With respect to §§ 70.64(b)(1) and (2), the NRC staff did not mean to imply that these provisions encompassed the defense-in-depth philosophy.

Comment A.8: One commenter recommended that the emergency capability baseline design criterion in § 70.64(a)(6)(ii) address on-site personnel (rather than all personnel). The commenter suggested that the rule language be rewritten as "*Evacuation of on-site personnel; and*…."

Response: The NRC agrees with the comment. The proposed change has been made and is consistent with the intent of the original rule language.

Comment A.9: One commenter stated that the criticality performance objective in § 70.61(d) is not related to §§ 70.61(b) or 70.61(c); yet, the three conditions are all linked together. The commenter suggested that subpart (d) should be segregated from (b) and (c) if (d) is preserved as an independent entry (as would seem preferable). Otherwise (d) should be subsumed under (b) and/or (c), and the regulatory basis for criticality prevention should be predicated on the risks and/or consequences of the accidents, rather than the presence of initiator precursor, per se.

Response: No change in the rule language has been made. The NRC believes that a separate performance requirement for nuclear criticality prevention is appropriate. The staff recognizes that many (but not all) nuclear criticality accidents would reasonably be expected to result in worker doses that exceed the high- and intermediate-consequence standards in § 70.61(b) or (c). However, regardless of the dose directly resulting from the accident, an inadvertent nuclear criticality should be avoided. This is consistent with the Commission's goal to prevent inadvertent criticalities, as reflected in the NRC Strategic Plan (NUREG-1614).

B. Content of Applications and ISA Summary

Comment B.1: One commenter stated that the rule should not prescribe an acceptable level of detail required in the application, but should defer this issue to the SRP. The commenter noted that, although progress has been made in certain areas (e.g., use of language such as "...types of accident sequences...."), in § 70.65(b)(6), which requires the applicant to list all items relied on for safety for high- and intermediate-consequence accidents, the required level of descriptive detail for items relied on for safety ("*sufficient detail*") remains vague. The commenter recommends that information at the "systems level" should be required, rather than at the "component" or "sub-component" level.

Response: The NRC disagrees with the comment. The current language permits the description of information at a systems level provided that there is enough detail to understand the function of the system in relation to the performance requirements. The degree of detail provided in the ISA Summary, with the other information available to NRC staff, must be sufficient for the NRC staff to make the determination specified in § 70.66 (i.e., that the performance requirements of the regulation are satisfied).

Comment B.2: One commenter stated that the list of items relied on for safety should not include procedures that the personnel must follow. According to the commenter, since procedures are constantly being adjusted, revised, and improved, their inclusion in the list of items relied on for safety would necessitate frequent revisions, to the ISA Summary, that may have little if any safety significance.

Response: § 70.65(b)(6) requires a list, in the ISA Summary, briefly describing each item relied on for safety. It does not require procedures to be listed in the ISA Summary. Therefore, the rule language permits the approach described in the comment. Typically, the actual *personnel action* would be regarded as an *item relied on for safety* and this would be expected to be addressed in the ISA Summary.

Comment B.3: Two commenters had concerns about the relationship among the ISA, the ISA Summary, and the safety program. One commenter recommended that the NRC clarify the relationship of the ISA Summary to the license and the safety basis to ensure consistency throughout the rule with the intent expressed in § 70.65(b). The commenter was concerned that the wording of § 70.65(a) is inconsistent with the idea, presented in § 70.65(b), that the ISA Summary will not be incorporated in the license. The commenter suggested removing the language in § 70.65(a) that references the inclusion of the ISA Summary in the license application, since that requirement is adequately covered in § 70.65(b). The commenter also recommended that a discussion of management measures be included as part of the ISA Summary. The second commenter stated that the rule implies that the ISA Summary, as part of the safety program, is part of the license. Further, the same commenter stated that the "Statement of Considerations" erroneously states that the results of the ISA must be submitted for NRC approval.

Response: The NRC generally agrees with the comment. The rule language in § 70.65(a) has been changed to remove the reference to the ISA Summary and management measures. This removes the implication that the ISA Summary is part of the license. With respect to the relationship of the ISA Summary to the management measures, although under the proposed rule, the elements of the ISA Summary did not explicitly include management measures, one of the elements [70.65(b)(4)] of the ISA Summary required information that demonstrates compliance with the performance requirements. Such a demonstration requires information about management measures. As suggested in the comment, the language in § 70.65(b)(4) has been clarified to explicitly include a description of the management measures. With regard to the comment that the “Statement of Considerations” erroneously “states that the results of the ISA must be submitted for approval”, the assertion that the “Statement of Considerations” is erroneous is incorrect - the “Statement of Considerations” is accurate. In response to this comment, and to clarify the role of the ISA Summary in licensing determinations, changes have been made to § 70.62(c)(3)(ii) and § 70.66. In particular, § 70.62(c)(3)(ii) has been modified to specifically state that the ISA Summary is submitted for approval consistent with the “Statement of Considerations” for the proposed rule. Section 70.66 states that this submission will be approved if the Commission determines that “the applicant has complied with the requirements of § 70.21, § 70.22, § 70.23, and § 70.60 through § 70.65.” The degree of detail provided in the ISA Summary [contents of the ISA Summary are described in § 70.65(b)] and the other information available, must be sufficient for the NRC staff to make the determination specified in § 70.66. To supplement staff understanding of information submitted, NRC may visit the facility during the licensing review to ensure a sufficient safety basis for operation.

Comment B.4: Two commenters were concerned with the broad nature of the requirement in § 70.65(b)(3) that seeks information on each process analyzed in the ISA, regardless of the risk associated with the process. According to one commenter, the ISA

Summary should only address those processes for which accident sequences have been identified that would produce consequences that exceed the performance criteria of § 70.61.

Response: The NRC staff needs some information on each process analyzed in the ISA to assess completeness and quality of the licensee's ISA process and to understand and assess the completeness and functions of the items relied on for safety. The degree of detail provided in the ISA Summary, together with the other information available, must be sufficient for the NRC staff to make the determination specified in § 70.66. In addition the information is useful in confirming the adequacy of emergency planning.

Comment B.5: According to one commenter, § 70.65(b) implies that the ISA Summary is a single document. In practice, the commenter noted that it will be a sequence of documents that cover the facility, and if multiple documents are submitted, they should all be in the same format.

Response: No change in the rule language has been made. The NRC agrees that the ISA Summary may consist of more than a single document; however, this is not precluded by the rule language.

Comment B.6: One commenter stated that the requirement, in § 70.65(b)(7), to provide information on the locations of onsite chemicals, is unnecessary.

Response: No change in the rule language has been made. Section 70.65(b)(7) does not require information on the locations of onsite chemicals to be submitted to the NRC. The regulation requires a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed material. This information is necessary to ensure safety and is consistent with NRC's Memorandum of Understanding (MOU) with the Occupational Safety and Health Administration (OSHA).

Comment B.7: One commenter objected to the requirement to provide process descriptions, noting that American Institute of Chemical Engineers (AIChE) guidelines may result in the process being broken into "nodes" or "segments." The commenter suggested that the rule should specify the descriptions of segments or nodes that could only be combined into a process if the boundaries established for the hazard analysis match.

Response: The NRC agrees with the comment, but does not believe a change in the rule language is needed. The intent of the § 70.65(b)(3) requirement is to provide process information so that the NRC staff can understand: what activities are performed at the site that involve hazardous materials associated with or produced from licensed radiological material, including any use, storage, manufacturing, or handling of those materials; what was analyzed in the ISA; and the hazards identified in the ISA. The AIChE guidelines use the term "process nodes" with respect to Hazard and Operability Analysis (HAZOP) and define it as "sections of equipment with definite boundaries...within which process parameters are investigated for deviations...." In HAZOP analyses, the term "node" designates a pipeline or vessel that has a common design intent. In meeting the § 70.65(b)(3) requirement, several nodes may be combined.

C. Safety Program

Comment C.1: Three commenters questioned the narrow definition of the safety program that is presented in § 70.62(a) and recommended deleting it from the rule language. According to the commenters, the safety program is broader than the three elements identified in § 70.62(a)(1) as process safety information, ISA, and management measures. The commenters noted that fuel cycle facility safety programs encompass the three elements identified plus all the other topics addressed in the license application. This includes, for example, radiation safety, criticality safety, chemical safety, and fire protection, in addition to the three elements directly associated with the ISA.

Response: NRC staff agrees in principle with the comment. The term "safety program," as used in § 70.62 (a), is related to the elements needed to demonstrate compliance with the performance requirements in § 70.61. This safety program consists of process safety information, ISA, and management measures. There is no intent to indicate that these elements represent the total safety program at the facility. Therefore, the rule language was clarified by changing "The three elements of the safety program; namely process safety information, integrated safety analysis, and management measures, are described in paragraph (b) through (d) of this section..." to "Three elements of this safety program; namely process safety information, integrated safety analysis, and management measures, are described in paragraph (b) through (d) of this section."

Comment C.2: One commenter stated that the current proposed rule offers sufficient flexibility in selecting ISA methodology so that a broad spectrum of facilities can be addressed and such that licensees have flexibility to interface with their site processes, procedures and resources.

Response: The Commission agrees with the comment; therefore, no change was made to the rule language with respect to ISA methodologies. The final rule offers sufficient flexibility in selecting an ISA methodology that can be used to analyze a facility's site, processes and procedures.

Comment C.3: Two commenters were concerned about the implementation of the final rule, and, in particular, the time frame for compliance with those aspects of the rule not related to the completion of the ISA and the submittal of the ISA Summary. One commenter, citing the experience when Part 20 was revised, recommended an effective date sufficiently far into the future so programmatic changes could be implemented at the operating facilities and any necessary conforming license amendments could be completed. Regarding the latter issue, both commenters cited 10 CFR 20.1008 as an example of how potential contradictions between license applications and regulations could be addressed. One commenter recommended including an additional provision of this type, especially in light of license conditions that have been added to licenses recently renewed by the NRC.

Response: The NRC agrees with the comment. In § 70.76(a), it states that "this provision shall apply for subpart H requirements as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66. For requirements other than Subpart H, this provision applies regardless of the status of the approval of a licensee's ISA Summary." In addition, Appendix A was revised to include the following: "Licensees must comply with reporting requirements in this appendix, except for (a)(1), (a)(2), and (b)(4), after they have submitted an ISA Summary in accordance with § 70.62(c)(3)(ii). Licensees must comply with (a)(1), (a)(2), and (b)(4) after (Insert 30 days after publication of this final rule)." In addition, § 70.62(c)(3)(ii) was revised to further clarify implementation schedules for existing licensees.

Comment C.4: Two commenters stated that a graded approach should be used in determining the management measures that need to be applied to items relied on for safety. One commenter recommended that the language in § 70.62(d) should be changed as follows: "*The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system*." The other commenter recommended that other factors besides risk including consequences, life cycle, and magnitude of hazard involved, should be used to determine appropriate management measures.

Response: The NRC agrees with the comment and has made the suggested change to the rule language in § 70.62(d). Regarding the question of considering other factors besides "risk," the NRC notes that the grading of measures to consequences, life cycle, and magnitude of hazard, is part of grading the measures to risk. The phrase used in the rule -- "commensurate with the reduction of risk attributable to that item" -- does not imply requiring a quantitative determination of the risk significance of any particular item relied on for safety. The rule is non-prescriptive regarding the grading approach and criteria to be used, allowing applicants to propose such details.

Comment C.5: One commenter stated that the 4-year period for conducting the ISA and for modifying the facility to address any identified unacceptable performance deficiencies may be too short and recommended a 5-year period instead. According to the commenter, a 5-year time-frame would be consistent with the time allowed for existing licensees that have committed, by license condition, to perform ISAs. The commenter also recommended that the period should start on the date when the NRC approves the plan required in § 70.62(3)(i), noting that if the clock starts on the effective date of the rule and the NRC takes one year to approve the ISA plan, the licensee will be unduly hampered. In addition, the commenter stated that there should be some incentive for the NRC to complete its approval process in a timely manner and recommended imposition of a 90-day limit for NRC to issue a decision on the acceptability of a licensee's ISA approach. The commenter also recommended that appropriate and sufficient time be allowed for the licensee to present a plan to the NRC and to implement the plan to correct any identified unacceptable performance deficiencies.

Response: Regarding the proposal for a 5-year period for conducting the ISA and correcting all unacceptable deficiencies, the NRC believes that the 4-year period proposed in the proposed rule is reasonable. However, NRC recognizes that there may be some instances where modifications resulting from the ISA cannot be completed within the 4 years specified and has modified § 70.62(c)(3)(ii) to accommodate these instances by clarifying that NRC may approve extensions for reasons that are beyond the control of the licensee. Regarding the licensee being unduly hampered because of the time required for the NRC staff to approve the plan required by § 70.62(c)(3)(i), the NRC staff expects to complete the licensing review within 90 days, assuming that the information submitted is complete. However, the time it takes the NRC to approve the plan will depend on the quality of the plan submitted by the licensee. In addition, current industry development of an ISA Summary guidance document should facilitate the licensing review process.

Comment C.6: One commenter stated that the plan required in § 70.62(c) which should be submitted within 6 months of the effective date of the rule, should pertain only if a licensee has not already completed the actions outlined in § 70.62(c)(3)(ii).

Response: The implementation plan and the ISA must satisfy the requirements in the final rule. If the actions outlined in § 70.62(c)(3)(ii) have been completed, then all that would be required to satisfy § 70.62(c)(3)(i) is submission of a description of any additional work that must be performed to meet the requirements in Subpart H of the rule, or a confirmation that the work submitted meets the requirements in Subpart H of the rule.

Comment C.7: Four commenters disagreed with the requirement in § 70.62(a)(3) to establish and maintain a log of failures of items relied on for safety. One commenter stated that the requirement should be rewritten to be performance-based rather than prescriptive. The commenter noted that most licensees have an incident reporting and corrective action system, which is used for all activities at the facility. As long as these systems meet the performance objective, it seems unnecessary for the rule language to be prescriptive in how it is met. Another commenter agreed, stating that it is inappropriate to impose this extra record-keeping burden on the licensee, because the licensee already has to generate records of this nature to manage its business and another different log is unnecessary work. Another commenter noted that because of the reporting requirements of § 70.62(a)(2) and

§ 70.74(a)(1), the NRC will already possess all of the information sought in the “log” of § 70.62(a)(3).

Response: The NRC generally agrees with the comment that maintenance of the failure log would be unnecessarily prescriptive. Regarding the concern about prescriptiveness, the rule has been revised to eliminate the requirement for licensees to establish and maintain a specific log of information developed and maintained elsewhere. However, the final rule requires that data be readily retrievable and available. This information is necessary to evaluate the reliability and availability of items relied on for safety, the likelihood of failure of the items, and the effectiveness of management measures implemented by the licensee. NRC also anticipates such information will be reviewed during periodic inspections by NRC as part of the revised oversight process that is being developed. Regarding the redundancy of reporting, the rule currently requires the licensee to report only any loss or degradation of items relied on for safety that results in failure to meet the performance requirements of § 70.61. The requirements of § 70.62(a)(3) include a much broader set of items, including all items relied on for safety or management measures that have failed to perform their function.

D. Change Process, License Renewal, and Backfit

Comment D.1: Five commenters were concerned about the requirement in § 70.72(d)(1) to submit changes to the ISA Summary every 90 days. Two commenters stated that an annual update [similar to the annual Final Safety Analysis Report updates for reactors per 10 CFR 50.71(e)] should suffice, considering that the potential consequences of reactor accidents are significantly greater than those at fuel cycle facilities. One commenter stated that an annual update to the ISA Summary would be consistent with the reporting requirements (for changes to records) of § 70.72(d)(3). Another commenter stated that the 90-day reporting of changes is entirely too frequent, which would mean that the facility and the NRC would always have change reporting in progress. According to the commenter, there is no need for NRC to have this "real-time" knowledge; rather, it is only important that the licensee have "real-time" knowledge. The commenter noted that the NRC only needs reasonably current knowledge, because the current ISA is available and accessible at the site. The commenter believes that a 12-month to 24-month update for reporting, as used in other places, is satisfactory and more efficient, noting that this seems clearly justified based on the fact that all the information is available at the site and accessible to the NRC at any time.

Response: The NRC agrees with the comment that submitting updates to the ISA Summary to the NRC can be less frequent than required in the proposed rule. The final rule retains quarterly (90-day reporting) only for changes related to the items relied on for safety; all other changes required in the proposed rule to be reported in 90 days would be changed to annually. Furthermore, the "90 days" in the proposed rule has been changed to "quarterly," to emphasize that the rule does not require continual reporting. Rather, all changes that affect the items relied on for safety that were made in a 3-month period (calendar quarter) can be reported at one time, within 30 days after the end of the period, and still meet the 90-day time period that was in the proposed rule.

The change reporting under 10 CFR Part 70 is consistent with the comparable requirements placed on reactor licensees. The final rule language is based on the analogy that "items relied on for safety" in Part 70 are generally equivalent to "technical specifications" in Part 50, because they both establish the safety envelope for licensed operations.

Considering the parallel between technical specifications and items relied on for safety, the final Part 70 requirement for reporting changes to NRC is less burdensome than the reporting requirements for reactors, when considering the differences in the respective change processes. In particular, for reactors, all changes to technical specifications must be pre-approved by NRC, effectively requiring the reporting of all changes to technical specifications before changes are made. The revised Part 70 language is not as restrictive -- it allows some changes to items relied on for safety to be made without NRC pre-approval and subsequently reported to NRC on a quarterly frequency.

A list of items relied on for safety that is reasonably up-to-date (i.e., at most 4 months out of date instead of 13 months out of date) would allow the NRC to know, on a relatively current basis, what a licensee is relying on to maintain the safety of the facility, and would allow the NRC to review, in a timely manner, the changes being made to the facility to ensure that the licensee's evaluations of changes have been conducted in accordance with the rule. Such information is also important to provide a clear understanding of the safety basis of the facility in support of subsequent licensing reviews, inspection planning, performance evaluation, and emergency response. The final rule permits licensees flexibility to make certain changes to the items that are relied on for the safety of the facility and still allow the NRC to be able to confirm the safety basis for the facility.

Comment D.2: One commenter noted that, under § 70.72, the NRC should define "periodically" in the context of reporting of changes made to SSCs etc.

Response: The NRC determined that no change to the reporting requirements is necessary in response to the comment. The comment referenced language in the "Statement of Considerations" not the rule. The specific reporting requirements were defined in the proposed rule and are included, as revised, in the final rule.

Comment D.3: Two commenters were concerned about the footnote, in § 70.72(c), which attempts to explain new types of accident sequences. Both commenters stated that the language in the footnote would require nearly all process changes to be approved by NRC through a license amendment, which would be in conflict with the overall objectives for the proposed rule. Both commenters recommended that the footnote be deleted.

Response: The NRC agrees that the footnote did not successfully clarify the definition of "new types of accident sequences." Thus, the footnote has been deleted from the final rule. The NRC staff will develop a guidance document, with input from stakeholders, to describe an acceptable change process that meets the requirements of the final rule in more detail.   The degree of detail provided in the ISA Summary, together with the other information available, must be sufficient for the NRC staff to make the determination specified in § 70.66. In addition, the staff had added a discussion to Chapter 3 of the SRP to describe an acceptable level of detail in the identification of the types of accident sequences.

Comment D.4: Three commenters were concerned about the requirements, in § 70.72, regarding configuration management and the overly broad process for making changes at licensed facilities. One commenter stated that the requirements, as written, apply to all site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, regardless of safety significance. The commenter noted that compliance with these requirements would appear to require configuration management and change control applied to everything on the site of the licensed facility; this could include the wastewater treatment facility, a laser facility, the administration building, maintenance of the shrubbery, etc. Every change would require an evaluation and a summary submitted to the NRC, yet inclusion in the change control process would make no contribution to the safety of licensed operations and would impose an undue burden on the licensee. To remedy this, the commenter recommended that the configuration and change process be limited to any "changes to the site, processes or items relied on for safety as described in the ISA Summary." Another commenter agreed, stating that the requirement is too broad and all-encompassing and would require configuration management evaluation of changes having no or absolutely minimal effect on health and safety (e.g. office remodeling, planting of shrubbery, changing paint colors). The commenter suggested that rather than control every change by means of configuration management, the licensee should first rely on internal procedures to screen any proposed changes initially for their potential safety significance.

Response: No change in the rule language has been made. The emphasis of this requirement is clearly on licensed operations and the associated safety controls. If a licensee has established a configuration management system in accordance with § 70.72(a), it is important the licensee use the system to evaluate every change made at a facility that could affect safety (i.e., generally not shrubbery, paint color) to ensure that any impacts from those changes on the safety of operations is identified, considered, documented, before implementing the change. In some cases, the analysis would be trivial because no known hazards would be involved in the change (e.g., certain changes in the administration building, or changes to shrubbery). Often it is clear that there are no safety implications associated with the proposed change. However, there may be special cases in which apparently minor changes could adversely affect safety, such as installation of a drinking water fountain in a radiological control area. In addition, every change which is assessed in the configuration management system does not need to be submitted to the NRC. Section 70.72(d)(3) states that only those changes to records required by § 70.62(a)(2) need to be submitted. These would include changes to the process safety information, ISA, and management measures. In addition, with respect to the use of an "initial screening" mechanism, the NRC staff considers an initial screening to assess the safety impact of a change to be part of an evaluation, as called for in

§ 70.72(a). In some cases, this screening will be sufficient.

Comment D.5: One commenter stated that §§ 70.72(c)(1)(i), (c)(2), and (c)(3) are wrong to use the ISA Summary as the decision-making document. The commenter noted that the ISA, the detailed licensee-generated information and evaluations that the licensee uses to manage its program comprises the information base for decisions. Summaries only provide a general level of information about the more important elements of the safety system for operations as determined under the licensed program.

Response: No change in the rule language has been made. The ISA Summary is prepared based on the ISA, and contains key information that is directly related to facility safety, such as a list of items relied on for safety, a description of hazards identified in the ISA, and a general description of the types of accident sequences. The contents of the ISA Summary are described in § 70.65(b). The NRC staff could review the adequacy of changes using the ISA instead of the ISA Summary, but this approach would require submission of a greater amount of information to NRC and would pose an unnecessary burden on the licensee. (Also, see response to Comment B.3).

Comment D.6: Two commenters are concerned about the annual requirement in § 70.72(d)(3) to submit a brief summary of all changes to the records required by § 70.62(a)(2). According to one commenter, the submittal would cover process safety information [§ 70.62(b)] including procedures, drawings, and detailed equipment lists. The commenter does not believe the NRC requires a summary of changes to this type information. A second commenter agreed, stating that the wording of this section will inadvertently and significantly expand the information that would have to be reported. In particular, the view was expressed that § 70.72(d) would require the licensees to submit voluminous information that could include the update to process safety information, including drawings, flow process diagrams, piping and instrumentation diagrams. The commenter suggested that this section should be reworded to read: "*a brief summary of all changes to the <u>integrated safety analysis and ISA summary</u>, that are made without prior Commission approval, must be submitted to the NRC every 12 months....*"

Response: No change in the rule language has been made. The regulation currently requires submission of "...brief summary of all the changes to the records required by § 70.62(a)(2)..." This does not require the submittal of actual charts and drawings but a written summary of the changes made. For the reasons cited in the response to comment D.1, it is important that the NRC be knowledgeable of changes made to this information.

Comment D.7: One commenter noted that, unlike § 50.59, the requirements of § 70.72 do not call for the submittal of a brief description and summary safety evaluation for each change. The commenter believes that the NRC would benefit from a description of changes made to the ISA Summary. Accordingly, § 70.72 should require brief descriptions and summary safety evaluations of each change made pursuant to § 70.72 and require that an updated ISA Summary be provided on a biennial basis.

Response: No change in the rule language has been made. The brief summaries of changes submitted under the requirements of § 70.72(d)(3) would be expected to include an explanation of each change, the reasons why the change was made, and why it did not require pre-approval. This information will be included in a guidance document to be developed. The NRC staff views this as sufficient and does not anticipate the need for licensees to submit a summary safety evaluation for each change, as long as each change has been made in accordance with the final rule and in accordance with the approved process.

Comment D.8: Two commenters questioned the current timeframe (10 years) or the need for renewal of licenses, suggesting that the new rule, in effect, resulted in a “living license.” One commenter stated that if a "living license" is truly the outcome as described in the “Supplementary Information,” renewal periods as long as 20 years would be appropriate. The other commenter noted that, with updates required every 12 months there is no real need for the NRC to renew the license – it only becomes a maintenance chore to confirm periodically that the licensing basis remains intact. The commenter believes that the living license concept provides advantages for the NRC and the licensee.

Response: Although the NRC generally agrees with those comments, no change in the rule language has been made. A specific time period for renewals is not specified in Part 70 and to establish one in the rule would require consideration of many factors, such as compliance with the National Environmental Policy Act and the impact of the loss of commitments linked to license renewal, that were not addressed in the current rulemaking (e.g., financial assurance for decommissioning). Establishment of a new term for licenses (e.g., 20 years) in 10 CFR 70 would require an analysis of these factors and an opportunity for public comment. The NRC staff will evaluate whether a longer term for fuel cycle licenses is appropriate in light of the new requirements in Subpart H. In any case, even if NRC ultimately declines to extend the term of the fuel cycle licenses (nominally 10 years), the burden of license renewal should be significantly reduced because the licensee will be required to maintain current the ISA Summary, items relied on for safety, and management measures.

Comment D.9: Five commenters recommended that a backfit provision similar to that in 10 CFR 50.109 or 10 CFR 76.76 should be included in the final rule. One commenter stated that the backfit provision should apply to current proposed changes at existing facilities. Another commenter stated that the backfit provision should be immediately effective for those processes or parts of an existing facility for which an ISA has been completed. A third commenter favored an immediately effective backfit provision. However, as an alternative, the commenter would make the provision effective for facilities or systems for which the ISA has been completed and the ISA Summary submitted to the NRC. A fourth commenter stated that deferring consideration of a backfit provision would be evading an extremely important issue, expressing the view that it is vital that a formal, systematic, and disciplined review of new, changed, or differing positions that could backfit existing facilities be applied to increase regulatory certainty. According to the commenter, no change to the backfit language in 10 CFR 50.109, which has been used successfully to control backfits at power reactors in the past, is needed to allow for qualitative analysis. 10 CFR 50.109, which the commenter endorses, is viewed as neither a quantitative nor a qualitative backfit provision. In contrast to the statement made in the Statement of Considerations of the proposed rule, the commenter does not believe that a comprehensive risk baseline is necessary before reasoned judgments can be made on the benefits and risks of a proposed backfit.

Response: The Commission agrees that regulatory stability and certainty can be improved by establishing a backfit provision for fuel cycle facilities covered by Subpart H of the final rule. Consequently, NRC has included a backfit provision in the rule in § 70.76. The wording of § 70.76 is similar to the current language in § 76.76 but does not include a "substantial increase in safety" test. For requirements other than Subpart H, this provision shall apply immediately after NRC publication of backfit guidance. For Subpart H requirements, this provision shall apply for a licensee as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66. The NRC will publish guidance that will address, among other matters, the qualitative versus quantitative analysis issue and consideration of chemical risks. The staff anticipates completing this guidance within six months of the publication of the final rule. Under the § 70.76 backfit provision, a backfit analysis is not required for modifications necessary to bring the facility into compliance with the rule, including the performance requirements in Subpart H. The subject of backfit is discussed in more detail in an attachment to
SECY-00-0111.

E. Definitions

Comment E.1: One commenter recommended a change (from 4 percent to 5 percent enrichment) in the definition of a *critical mass of SNM* to reflect the higher enrichments that are currently in use.

Response: The definition of *critical mass of SNM* in Part 70 is used solely to determine when Subpart H applies. To emphasize this point, the definition was changed to include the phrase, "for purposes of subpart H." The definition, including the 4 percent figure, is identical to that used in § 70.24, which requires criticality accident alarms and other related measures.

Comment E.2: Regarding the issue of "reasonable assurance," two commenters stated that, in the definition of *available and reliable to perform their function when needed*, the use of the term "ensure" implies a level of certainty that is unrealistically high. Both commenters recommended replacing the term "ensure" with the term "provide reasonable assurance." One commenter also recommended removing the word "continuous" from the definition, which would now read "…*means that…items relied on for safety will perform their intended safety function when needed and management measures will be implemented to <u>provide reasonable assurance of</u> compliance with the performance requirements of § 70.61.*"

Response: The definition was revised to remove the word "continuous," but no change was made regarding "ensure." With respect to "ensure," the proposed rule language does not indicate a level of certainty that is unrealistic. The term "ensure" is used extensively throughout NRC's regulations in the context of a licensee's obligations to connote "make sure" or “make certain.” Specifically, elsewhere in Part 70 alone, the term is used in this context eight times: §§ 70.24(a)(3), 70.32(j), 70.38(g)(4)(iii), 70.51(a)(10), 70.52(c), 70.57(b)(3), 70.57(b)(4), and 70.57(b)(6). Whereas, the term “reasonable assurance” is used just once in Part 70, in § 70.23(b), to describe the level of assurance that the Commission must find in order to approve construction. The use of “ensure” in the definition of *“available and reliable to perform their function when needed*'” in § 70.4 is appropriate. In short, licensees “ensure” and the Commission determines “with reasonable assurance.” Regarding the issue of “continuous compliance,” the definition of “available and reliable” in § 70.4 has been modified to delete the word “continuous.” This change recognizes the concept that a failure of an item relied on for safety does not automatically infer a failure to meet the performance requirements of § 70.61. In addition, the NRC recognizes that items relied on for safety may temporarily not be available (i.e., not continuous) when taken out of service for maintenance or functional testing; however, the performance requirements must still be met. A discussion has been added to Chapter 3, in the SRP, to address the relationship of failures of items relied on for safety to meeting the performance requirements.

Comment E.3: One commenter stated that there is a “disconnect” regarding the definition of the term *items relied on for safety* and recommends that the term be replaced by the term *Measures relied on for safety.*

Response: The reason for the comment is not clear, but perhaps the commenter objects to the use of the term “item” to refer to a personnel action. Part 70 does, in fact, allow human actions to be items relied on for safety and permits flexibility in determining how the *items* and *measures* are defined. Consequently, the Commission has retained the original text in the final rule. (See related Comments B.2. and E.4.)

Comment E.4: One commenter was concerned that the term *items relied on for safety* includes "activities of personnel," and proposed changing the definition in 70.4 to limit items relied on for safety to "structures, systems, equipment, and components."   According to the commenter, it is reasonably straightforward to classify physical items as being relied upon for safety, and to apply graded quality assurance controls, including management measures, to design, construction, operation, and maintenance, etc., of those physical items, based on their respective safety functions. The commenter stated that it can be confusing to try and classify and grade items when they include "personnel activities," since an activity has little importance absent the context of its influence on a physical item's safety function. Removing "personnel activities" from the definition of items relied on for safety would not limit their importance but rather, would put activities in context with the structures, systems, equipment, or components to which they are related, without necessitating a change in the balance of the proposed rule. The commenter stated that removing personnel activities from the definition of items relied on for safety will also help address the concern raised (in comment B.2) regarding the treatment of procedures as items relied on for safety.

Response: No change was made to the rule language. Human actions that are relied on to prevent an accident (i.e., administrative controls) are as important as the "physical items" needed to prevent an accident. Just as there are measures (e.g., maintenance, configuration management) needed to ensure the availability and reliability of physical controls, there are analogous measures (e.g., training, procedures) needed to ensure the availability and reliability of human actions. Graded approaches that can be applied to the maintenance of a physical control depending on the risk significance of the control could also be applied to the training of workers who perform safety functions, depending on the risk significance of the human's actions. Although the reliability of engineered controls may be higher than administrative controls, the final rule allows licensees the flexibility to employ both engineered as well as administrative controls

Comment E.5: One commenter stated that the NRC should define the terms *likely, unlikely, highly unlikely,* and *credible* in the rule so that there will be one set of definitions applied to all nuclear fuel facilities. The commenter stated that this will minimize the interpretation and application of these terms in the ISA.

Response: No change in the rule language has been made. Part 70 applies to different types of fuel cycle facilities, some of which are more complex and have more accident sequences than others. Accordingly, since the application of the terms in the rule will be necessarily specific to the individual context in which they are applied, the development of a definition for these terms in the rule language is impracticable. The Commission, however, will provide general guidance on the application of the terms *unlikely* and *highly unlikely* in the SRP to aid licensees in implementing the provisions of the rule.

Comment E.6: One commenter recommended a change in the definition of *worker.* In particular, the language "...exposure to radiation and /or radioactive material from licensed and unlicensed sources of radiation" would be replaced with "...exposure to radiation and /or radioactive material from licensed sources of radiation, and radiation from man-made non-regulated sources (e.g., an individual)." As originally defined, persons who are subject to occupational doses from natural sources of radiation, (e.g., airline pilots and astronauts subject to high cosmic background might be included, whereas workers involved with the possession or use of unlicensed radioactive materials might not be). The commenter stated that the proposed change removes this source of confusion.

Response: The NRC staff agrees in principle with the comment. However, the commenter's proposed change does not eliminate the confusion (e.g., some man-made unlicensed sources of radiation are part of background or otherwise not included in occupational doses as defined in NRC's radiation protection standards in 10 CFR 20). Instead, in response to the comment, the definition in § 70.4 was changed to: *Worker*, as used in Subpart H, means an individual who receives an *occupational dose* as defined in 10 CFR 20.1003.

F. Miscellaneous

Comment F.1: One commenter recommended that the criticality requirements of § 70.24 be revised to permit alternate criticality control provisions to be accepted for DOE facilities without requiring an exemption.

Response: Comments on § 70.24 are outside the scope of the rulemaking.

Comment F.2: Two commenters recommended changes in the decommissioning requirements of §§ 70.22(a)(9) and 70.38. In particular, one commenter recommended that the timeliness and schedule provisions in the decommissioning requirements of § 70.38 be revised to include separate requirements for DOE facilities.

Response: Comments on §§ 70.22(a)(9) and 70.38 are outside the scope of the rulemaking.

Comment F.3: One commenter expressed concern with the language in § 70.23(b), which states that the Commission will approve construction of a plutonium processing and fuel fabrication facility only after determining that the design bases of SSCs, and the attendant quality assurance program are adequate to protect against natural phenomena and the consequences of potential accidents. In particular, the commenter stated that this provision, as written, seems contrary to other changes being proposed under the draft rule, because it addresses consequences of potential accidents, as opposed to the risk associated with credible accidents.

Response: Section 70.23(b) has not been modified in this rulemaking. The reference to "consequences" in the rule language does not preclude a risk-informed approach in satisfying this requirement. The NRC will need to consider the risk, and thus the likelihood of consequences of potential accidents occurring, in order to determine whether there is reasonable assurance of protection against such consequences. Such consideration of risk will be important in determining the need for (and the ability of) the applicant to reduce the likelihood of accidents and to mitigate their consequences.

Comment F.4: One commenter recommended that § 70.11 be revised to reflect the applicability of NRC authority over a MOX fuel fabrication facility owned by the DOE, pursuant to changes in law last year.

Response: The NRC agrees with the comment, but believes a separate rulemaking is required. Since October 17, 1998, when the amendment to Section 202 of the Energy Reorganization Act of 1974 was enacted, § 70.11, as well as several other subsections of the regulations, need to be updated to reflect this legislative change. However, to address this subsection and all the other instances, and to avoid the necessity for potential future revisions of this type, the NRC intends to institute an administrative-type rule amendment to conform all of the references to Section 202 in the regulations, including § 70.11, to merely cite Section 202, rather than repeat the text of that section. Because this rule change affects various parts of the regulations, it will be conducted independently of the current Part 70 amendments.

Comment F.5: One commenter stated that as additional DOE facilities are licensed by the NRC under Part 70, the NRC should ensure that the requirements address the full range of fissionable and fissile materials at these facilities.

Response: This issue is beyond the scope of the rulemaking. It will be addressed, if necessary, in the future.

Comment F.6: One commenter agreed that the proposed rule is entirely consistent with the U.S. Environmental Protection Agency’s Risk Management Program regulations and the general duty clause of the Clean Air Act, and contains appropriate complementary safety measures for facilities possessing a critical mass of SNM.

Response: No response necessary.

Comment F.7: One commenter strongly recommended that the NRC adopt, by reference, the 1998 edition of National Fire Protection Association (NFPA) 801, "Facilities Handling Radioactive Materials." NFPA 801 would apply to § 70.62, "Safety program and integrated safety analysis," which addresses protection from all relevant hazards, including radiological, criticality, fire, and chemical. The NFPA standard would also apply to § 70.64, "Requirements for new facilities or new processes at existing facilities," which addresses fire protection. The reference to NFPA 801 is in keeping with the requirements of Public Law 104-113 *"National Technology Transfer and Advancement Act,"* which requires Federal agencies to use private sector-developed national consensus technical standards in carrying out public policy, wherever appropriate.

Response: The suggested change would be an unnecessarily prescriptive rule requirement. Instead, the NRC identifies the standards in NFPA 801 and 600 as an acceptable approach for demonstrating compliance with 10 CFR Part 70 in the SRP.

Comment F.8: One commenter noted that the proposed rule incorporates the current terms of the MOU between the NRC and OSHA. This should avoid misunderstanding and result in more effective implementation for all concerned parties.

Response: Although the rule is consistent with the NRC-OSHA MOU, the rule itself does not incorporate the terms of the MOU. Nevertheless, the NRC agrees with the spirit of the comment.

Comment F.9: Two commenters expressed concern over those portions of §§ 70.22 and 70.23 of the existing rule that address the regulation of plutonium processing and fuel fabrication facilities. One commenter asked if § 70.22 (f) should be coordinated with § 70.65. The commenter noted that it is not clear if the requirements are collateral, complementary, or redundant. The same commenter stated that § 70.23(b) should be examined to clarify the need for this requirement in light of similar information being submitted pursuant to § 70.65. The second commenter agreed, stating that § 70.22(f) requires plutonium-related applicants to provide information on the facility site and design basis of principal SSCs, etc., as part of the license application. The commenter believed that this information is also required in other sections of the revised rule, and thus is redundant.

Response: No change in the rule language has been made. The requirements are not viewed as redundant, considering: the timeframe for submittal of information required by the two sections could be different; and § 70.23(b) contains a requirement for NRC construction approval before the start of construction.

Comment F.10: Two commenters were concerned about the construction authorization provisions in § 70.23(b) and 70.23(a)(7). According to one commenter, irrespective of § 70.65, the construction authorization provision in § 70.23(b) appears to be an unnecessary step and should be considered for deletion by the NRC. If the NRC chooses to retain § 70.23(b), the

NRC should clarify how the authorization process would be conducted, given that the procedural step has never been exercised. Furthermore, the NRC should identify how the "design basis" authorization is defined, why it is necessary, and how it relates to the ISA. The second commenter noted that § 70.23(a)(7), which applies to other Part 70 licensees, allows construction to commence based on a conclusion by the Director, NRC Office of Nuclear Material Safety and Safeguards, that environmental impacts have been appropriately addressed. The commenter stated that this discretion afforded the NRC under § 70.23(a)(7) – i.e., NRC's authority over construction associated with "any…activity which the Commission determines will significantly affect the quality of the environment" is adequate to ensure the sufficiency of information provided to the NRC to authorize or disallow construction. The commenter proposes that § 70.23(a)(7) be clarified for applicability to plutonium facilities, and that §§ 70.22(f), 70.23(a)(7),and 70.23(b) be eliminated. Doing so would avoid the preconception that, irrespective of design features and material composition, plutonium is "more special" than other SNM.

Response: No change in the rule language has been made. The Atomic Energy Commission specifically established these requirements (see 36 FR 9786; May 28, 1971 and 36 FR 17573; September 2, 1971) for plutonium facilities in recognition of the potential exposures and ground-contamination levels that may result if only a small fraction of the dispersible plutonium in process were released (see SECY-R 188, March 17, 1971). The current revisions to Part 70 do not impact this section and therefore, the suggested change is outside the scope of the rulemaking. Regarding the authorization process, the NRC staff has clarified this process in a letter to Duke, Cogema, Stone & Webster, dated September 10, 1999. The design basis was also identified in this letter. NRC provided additional guidance on this process in the draft Standard Review Plan for a Mixed Oxide Fuel Fabrication Facility. In addition, the NRC staff is currently assessing the opportunities for hearings associated with the review of a license application for a plutonium processing facility and may offer additional guidance on this topic later in 2000.

Comment F.11: One commenter noted that, under § 70.23(a)(8), the NRC will approve a plutonium facility's license application only after construction of principal SSCs has been completed in accordance with the application. Certainly this is not a requirement unique to plutonium facilities. The NRC already has the authority to grant licenses conditional on successful completion of certain actions (such as successful start-up testing, training, etc.). Completion of construction in accordance with the license application seems such an obvious condition that this specific provision seems redundant and therefore unnecessary.

Response: The NRC established § 70.23(a)(8) specifically for plutonium processing facilities. Because the current revisions to Part 70 do not impact this section, comments regarding this section are outside the scope of the rulemaking. See response to Comment F.10.

Comment F.12: One commenter noted that the terminology in Appendix A (b)(1) clearly ties the failure to the performance requirements. The phrase, "and which results in failure to meet the performance requirements of § 70.61" is very clear. This phrase should be consistently included in Appendix A (b)(2)-(5) using the exact same wording.

Response: No change in the rule language has been made. The linkage to the failure to meet the performance requirements is already included in Appendix A (b)(2) and (b)(3). For the events described in Appendix A (b)(4) and (5), the NRC staff desires to be informed when such events occur, regardless of the licensee's determination with respect to the performance requirements. In these cases, the NRC staff will independently confirm the licensee's assessment of whether the performance requirements were met, on the basis of the information reported.

Comment F.13: One commenter stated that the reporting requirements of § 70.50 continue to misrepresent the principles of the 1988 NRC-OSHA MOU. Section 70.50(c)(1)(iii)(A) requires the reporting of chemical hazards and § 70.50(c)(1)(iii)(B) requires the reporting of personnel exposures to chemicals. According to the commenter, although the MOU principles have been correctly incorporated into other proposed revisions to Part 70 (e.g., §§ 70.4, 70.61(b), 70.62(c), 70.64(a), 70.74, and Appendix A), they were incorrectly referenced in § 70.50. MOU principle (2) limits NRC jurisdiction to regulation of chemical hazards of licensed material and hazardous chemicals <u>produced from licensed material</u>. The two aforementioned sections of § 70.50 should be corrected to properly incorporate the MOU principles.

Response: The rule was revised in response to the comment to reflect more precisely the language in the NRC-OSHA MOU.

Comment F.14: One commenter noted that applicants for licenses to operate new facilities or new processes at existing facilities would be expected ("Statements of

Consideration,” 64 FR 41346) to update their ISAs, based on as-built conditions, and submit the results to the NRC before operation. The process for uranium enrichment facilities that must comply with § 70.23a would differ from this description. Uranium enrichment facilities would submit a complete license application, including an ISA Summary, for construction and operation. This application would be the basis for NRC review, and culminate in issuance of a license for construction and operation. After issuance of the license, the licensee would institute change control under § 70.72. The licensee would then be required to submit summaries of changes and ISA Summary updates as required by § 70.72. An inspection would verify that the facility has been constructed in accordance with the license, before operation, as required by § 70.32(k). No pre-operational submittal and review of an updated ISA Summary are anticipated for uranium enrichment facilities because their configuration would be controlled after issuance of the construction and operation license.

Response: As recognized by the commenter, no changes to the rule are necessary. The differences in the licensing process for enrichment facilities other than the gaseous diffusion plants (regulated under 10 CFR Part 76) reflect the process mandated in Section 193 of the Atomic Energy Act of 1954, et. seq.

III. Changes from the Proposed Rule

Subpart A - General Provisions

AUTHORITY

This section has been changed to reflect the redesignations of §§ 70.61 and 70.62 as §§ 70.81 and 70.82, respectively.

§ 70.4 Definitions.

The definition of “available and reliable to perform their function when needed” has been modified to eliminate the need to maintain “continuous” compliance with the performance requirements of § 70.61. The definition of “configuration management” has been modified to clarify its role as a “management measure.” The definition of “critical mass of special nuclear material” has been modified to emphasize that the definition is only for the purposes of Subpart H. The definition of “double contingency” has been changed to provide minor clarification. The definition for “worker” has been clarified and has been revised to emphasize that the definition is only for purposes of Subpart H.

Subpart G - Special Nuclear Material Control Records, Reports, and Inspections

§ 70.50 Reporting requirements.

The reporting requirements for hazardous chemicals have been revised to be consistent with the language of the 1988 NRC-OSHA MOU (53 FR 43950; November 22, 1988).

Subpart H - Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material

§ 70.60 Applicability.

The applicability of the Subpart H requirements has been revised to clarify when the requirements will take effect.

§ 70.61 Performance requirements.

The performance requirements in §§ 70.61(b) and (c) have been revised to provide clarification. The requirement to establish a controlled area in § 70.61(f) has been revised to clarify the conditions for establishing the controlled area, and to clarify the applicability of the performance requirements to individuals within the controlled area. The requirement in § 70.61(f)(2) to provide training "in accordance with" 10 CFR 19.12(a)(1)-(5) has been revised to clarify that equivalent training is acceptable. The new language specifies that such training must "satisfy" 10 CFR 19.12(a)(1)-(5).

§ 70.62 Safety program and integrated safety analysis.

The requirement to establish and maintain a safety program in § 70.62(a)(1) has been revised to clarify that the safety program referred to in this section is focused on the safety program for satisfying the new Subpart H requirements, and that the application of management measures may be graded according to risk. Section 70.62(a)(3) has been modified to make it performance-based by eliminating the prescriptive requirement to maintain a log of failures for items relied on for safety. Section 70.62(c)(3) has been revised to clarify the contents of the ISA Summary, and clarify the schedule for planning and performing an ISA, correcting all performance deficiencies, and submitting the ISA Summary to the NRC for approval. The approval process for the ISA Summary will require the issue of a license amendment; however, a license condition will be established that allows the licensee to make changes in accordance with § 70.72, including certain changes that do not require prior NRC approval. In addition, a provision has been added to the schedule for complying with the requirements in subpart H for factors beyond control of the licensee. This would allow additional time for correcting a performance deficiency if the NRC approves.

§ 70.64 Requirements for new facilities or new processes at existing facilities.

Section 70.64(a) has been revised to provide the correct reference, § 70.62(c), to the performance of an ISA. Section 70.64(a)(6)(ii) has been modified to specify that the required emergency capability is concerned with the evacuation of only on-site personnel.

§ 70.65 Additional content of applications.

Section 70.65(a) has been revised to clarify that the ISA Summary is not part of the safety program description required for inclusion in the license application. Rather, the ISA Summary, which contains a description of management measures, is submitted with the license application.

§ 70.66 Additional requirements for approval of license application.

Section 70.66(b) has been added to clarify, for existing licensees, the basis for Commission approval of: the ISA plan, submitted under § 70.62(c)(3)(i), and the ISA Summary, submitted under § 70.62(c)(3)(ii).

§ 70.72 Facility changes and change process.

Section 70.72(c)(1) has been revised to eliminate the footnote, which did not adequately clarify the meaning of "new types of accident sequences." Sections 70.72(d)(1) and 70.72(d)(3) have been changed to reflect a modified schedule for submission of revised pages to the ISA Summary.

§ 70.76 Backfitting.

Section 70.76 was added to include requirements for performing a backfit analysis. The wording in § 70.76 is similar to the current language in §76.76 for gaseous diffusion plants with two exceptions, sections 70.76 (a)(3) and 70.76 (a)(4)(i). The first exception in § 70.76(a)(3) relates to a change of the standard from "substantial increase" to "increase" and is responsive to Commission direction in an SRM dated December 1, 1998, on the draft proposed rule. The second exception in § 70.76(a)(4)(i) relates to the backfit requirements being inapplicable to changes associated with bringing the facility in compliance with the requirements of the new subpart H. The backfit section includes a provision stating that it shall apply for subpart H requirements as soon as NRC approves that licensee's ISA Summary (contents of ISA Summary described in § 70.65(b)) pursuant to § 70.66 and, for requirements other than Subpart H, it shall apply immediately after NRC publication of backfit guidance.

§ 70.92 Criminal Penalties.

This section has been changed to reflect the redesignations of §§ 70.13a, 70.14, 70.61, 70.62, 70.71, and 70.72 as §§ 70.14, 70.17, 70.81, 70.82, 70.91, and 70.92, respectively, and the addition of §§ 70.66, 70.73, and 70.76.

IV. Section-by-section Analysis of Part 70 Amendments

AUTHORITY

This section has been changed to reflect the redesignations of §§ 70.61 and 70.62 as §§ 70.81 and 70.82, respectively.

Subpart A - General Provisions

§ 70.4 Definitions.

Definitions of the following 12 terms have been added to this section to clarify the meaning of certain terms and phrases used in the new Subpart H: “Acute,” “Available and reliable to perform their function when needed,” “Configuration management,” “Critical mass of SNM,” “Double contingency,” “Hazardous chemicals produced from licensed materials,” “Integrated safety analysis,” “Integrated safety analysis summary,” “Items relied on for safety,” “Management measures,” “Unacceptable performance deficiencies,” and “Worker.”

§ 70.14 Foreign military aircraft.

This section reflects an administrative change to designate this section, formerly § 70.13a.

§ 70.17 Specific exemptions.

This section reflects an administrative change to designate this section, formerly § 70.14.

Subpart G - Special Nuclear Material Control Records, Reports, and Inspections

§ 70.50 Reporting requirements.

Paragraph (c) has been reworded to include information to be transmitted when making verbal or written reports to the NRC. The new information derives from the specifics of the new Subpart H, such as sequence of events and whether the event was evaluated in the ISA. To the extent the new information is also applicable to licensees not subject to Subpart H, the information was added with no differentiation noted. The new information that would only apply to Subpart H licensees is noted.

Subpart H - Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material

§ 70.60 Applicability.

This section lists the types of NRC licensees or applicants that are subject to the new Part 70, Subpart H, and describes when the new requirements will be effective.

§ 70.61 Performance requirements.

This section identifies the performance requirements that licensees subject to Part 70, Subpart H must satisfy. These performance requirements explicitly address the risks to workers or members of the public and the environmental releases caused by accidents. Because accidents are unanticipated events that usually occur over a relatively short period of time, the Part 70 changes seek to ensure adequate protection of workers, members of the public, and the environment by limiting the risk (product of likelihood and consequence) of such accidents. If, without the implementation of controls, a high consequence event under § 70.61(b) is highly unlikely, then it is not necessary for the licensee to apply the engineered or administrative controls mentioned in the rule. Similarly, if, without the implementation of controls, an intermediate consequence event under § 70.61(c) is unlikely, then it is not necessary for the licensee to apply the engineered or administrative controls mentioned in the rule.

§ 70.62 Safety program and integrated safety analysis.

This section describes requirements for establishing and maintaining a safety program that demonstrates compliance with the performance requirements of § 70.61. The elements of this safety program include the compilation of process safety information, the performance of an ISA, and the application of management measures to ensure the availability and reliability of items relied on for safety.

§ 70.64 Requirements for new facilities or new processes at existing facilities.

This section describes baseline design criteria for new facilities or new processes at existing facilities. The application of these criteria, which are similar to the general design criteria in Part 50, Appendix A; Part 72, Subpart F; and 10 CFR 60.131, are consistent with good engineering practice, which dictates that certain minimum requirements be applied as design and safety considerations for any new nuclear process or facility. The baseline design criteria do not provide relief from compliance with the performance requirements of § 70.61.

§ 70.65 Additional content of applications.

In addition to the information that currently must be submitted to the NRC under § 70.22, for a license application, this section requires additional information to be submitted to demonstrate compliance with the new subpart H requirements. In particular, this additional information includes a description of the applicant's safety program established under § 70.62.

This information will be incorporated in the license, as appropriate. The ISA Summary must be submitted with the license application, but will not be incorporated in the license.

§ 70.66 Additional requirements for approval of license application.

This section contains the provision that the applicant must comply with the requirements of §§ 70.60 through 70.65 (in addition to §§ 70.21 through 70.23, in the existing regulation) before a license will be granted. It also contains the requirements for approving the ISA plan and the ISA Summary for existing licensees.

§ 70.72 Facility changes and change process.

This section contains requirements that govern changes to site, structures, systems, equipment, components, and activities of personnel after a license application has been approved. It requires the licensee to establish and use a configuration management system to evaluate changes and the potential impacts of those changes before implementing them. The regulation permits the licensee to make certain changes without NRC pre-approval, but requires the licensee to submit a brief summary of the changes plus updated ISA Summary pages every 12 months. A quarterly report is required for changes to items relied on for safety that are not subject to pre-approval.

§ 70.73 Renewal of licenses.

This section contains the requirements for renewing licenses. It references the existing renewal requirements and the additional contents of application in § 70.65.

§ 70.74 Additional reporting requirements.

This section contains new requirements, in addition to those in existing Parts 20 and 70, for reporting events to the NRC. The new approach, based on consideration of the performance requirements established in 10 CFR 70.61(b), is intended to eventually replace and modify the approach licensees have currently been using for reporting criticality events under NRC Bulletin 91-01. The new approach would cover all types of events, not just criticality events, and establish a timeframe for reporting that is scaled according to risk.

§ 70.76 Backfitting.

This section contains requirements for performing a backfit analysis that are based on those in 10 CFR 76.76. It will become effective after NRC publication of backfit guidance. The NRC will publish a separate Federal Register notice upon publication of the guidance to indicate the effectiveness of § 70.76. After that notice is published, this provision will not be applied for Subpart H requirements until the NRC approves the licensee's ISA Summary pursuant to
§ 70.66.

Subpart J - Enforcement

§ 70.92 Criminal penalties

This section has been changed to reflect the redesignations of §§ 70.13a, 70.14, 70.61, 70.62, 70.71, and 70.72 as §§ 70.14, 70.17, 70.81, 70.82, 70.91, and 70.92, respectively, and the addition of §§ 70.66, 70.73, and 70.76.

Appendix A Reportable safety events.

This appendix contains a list of events that licensees must report to the NRC. These events are categorized according to their consequences (or potential consequences) and fall into two classes: a 1-hour or 24-hour reporting timeframe. The emphasis on consequences, rather than risk, is appropriate in this case because the event has already occurred. Appendix A also requires concurrent reporting of events when a news release is made or if other Government agencies are notified, as is done under 10 CFR 50.72, to enhance coordination and support NRC's ability to be respond to questions concerning the safety of NRC-licensed facilities.

V. Finding of No Significant Environmental Impact: Availability

The Commission has determined, under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required.

The amendments to 10 CFR Part 70 are intended to provide increased confidence in the margin of safety at certain facilities that possess a critical mass of SNM. To accomplish this objective, the amendments: (1) identify appropriate performance requirements and the level of protection needed to prevent or mitigate accidents that exceed such requirements; (2) require affected licensees to perform an ISA to identify potential accidents at the facility and the items relied on for safety; (3) require the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their functions when needed; (4) require the safety bases to be maintained, and changes reported to the NRC; (5) allow for licensees to make certain changes to their safety program and facilities without prior NRC approval; (6) require reporting of certain events; and (7) require a backfit analysis under specified conditions.

The rule language that defines the performance requirements is relevant to the question of environmental impact. Licensees are required to protect against the occurrence of or to mitigate the consequences of accidents that could adversely affect workers, the public, or the environment. For example, licensees are required to provide an adequate level of protection against a “release of radioactive material to the environment outside the restricted area in concentrations that, if averaged over 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20.” Implementation of the new amendments, including the requirement to protect against events that could damage the environment, is expected to result in a significant improvement in licensees’, NRC’s, other governmental agencies’, and the public’s understanding of the risks at these facilities and licensees’ ability to ensure that those risks are appropriately controlled. For existing licensees, any deficiencies identified in the ISA (which must be completed within 4 years) will need to be promptly addressed. For new licensees, operations will not begin unless licensees demonstrate an adequate level of protection against potential accidents identified in the ISA. As a result, the safety and environmental impact of the new amendments is positive. There will be less potential adverse impact on the environment from licensed operations carried out under the final rule than if those operations were carried out under the existing Part 70 regulation. Thus, the Commission has determined, based on the Environmental Assessment that supports the rule, that there will be no significant impact on the human environment from this action.

The NRC requested public comments on any environmental justice considerations that may be related to this rule. No comments were received in response to this request.

The NRC also requested the States’ views on the environmental assessment for this rule. No comments were received in response to this request.

The Environmental Assessment is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. Single copies of the Environmental Assessment are available from Barry Mendelsohn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, telephone (301) 415-7262; e-mail: btm1@nrc.gov.

VI. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0009.

The public reporting burden for this information collection is estimated to average 99 hours per response. The recordkeeping burden is estimated to average 560 hours per licensee, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at bjs1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0009), Office of Management and Budget, Washington, DC 20503.

VII. Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

VIII. Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. Single copies of the environmental assessment are available from Barry Mendelsohn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, telephone (301) 415-7262; e-mail: btm1@nrc.gov.

IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act, as amended, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The regulation affects facilities that are authorized to possess a critical mass of SNM and that are engaged in one of the following activities: enriched uranium processing; fabrication of uranium fuel or fuel assemblies; uranium enrichment; enriched uranium hexafluoride conversion; plutonium processing; fabrication of mixed-oxide fuel or fuel assemblies; scrap recovery of SNM or any other activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety or the environment. These licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, nor the size standards published by the NRC (10 CFR 2.810).

X. Voluntary Consensus Standards

The National Technology Transfer Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this regulation, the NRC will use the following voluntary consensus standard -- ANSI/ANS Standard 8.1-1983, "Nuclear Criticality Safety in Operations with Fissionable Material Outside Reactors" developed by the American Nuclear Society. Portions of the standard were used in the definition of double contingency and in § 70.61(d). A consensus standard with the complete scope of the requirements established in this rulemaking does not exist. The Commission will reference ANS 8.1 and other consensus standards, as appropriate, as acceptable approaches to demonstrate compliance with specific portions of the final rule. This will be addressed in the Standard Review Plan that is being established along with the rule.

XI. Backfit Statement

The NRC has determined that the backfit rule does not apply to this final rule; therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. However, future changes to the requirements in subpart H or NRC requirements that apply to facilities covered by subpart H will be subject to the backfit requirements in § 70.76 established in this rule.

XII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

XIII. List of Subjects

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to Part 70.

PART 70--DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

1. The authority citation for part 70 is revised to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42

U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104-134, 110 Stat. 1321, 1321-349 (42 U.S.C. 2243).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93-377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

2. The undesignated center heading ``GENERAL PROVISIONS'' is redesignated as “Subpart A--General Provisions.”

3. In § 70.4, the definitions of Acute, Available and reliable to perform their function when needed, Configuration management, Critical mass of special nuclear material, Double contingency, Hazardous chemicals produced from licensed material, Integrated safety analysis (ISA), Integrated safety analysis summary, Items relied on for safety, Management measures, Unacceptable performance deficiencies, and Worker are added, in alphabetical order, as follows:

§ 70.4 Definitions.

* * * * *

Acute, as used in this part, means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

* * * * *

Available and reliable to perform their function when needed, as used in subpart H of this part, means that, based on the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function when needed, and management measures will be implemented that ensure compliance with the performance requirements of § 70.61 of this part, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the items and measures.

. . . . * * * * *

Configuration management (CM) means a management measure that provides oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their functions when needed.

. . . . * * * * *

Critical mass of special nuclear material (SNM), as used in Subpart H, means special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.

* * * * *

Double contingency principle means that process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

* * * * *

Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.

* * * * *

Integrated safety analysis (ISA) means a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety. As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this part, the NRC requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.

* * * * *

Integrated safety analysis summary means the document submitted with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety analysis and contains the information specified in § 70.65(b).

* * * * *

Items relied on for safety mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

* * * * *

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.

* * * * *

Unacceptable performance deficiencies mean deficiencies in the items relied on for safety or the management measures that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).

* * * * *

Worker, when used in Subpart H of this Part, means an individual who receives an occupational dose as defined in 10 CFR 20.1003.

4. In § 70.8 paragraph (b) is revised to read as follows:

§ 70.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 70.9, 70.17, 70.19, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.25, 70.32, 70.33, 70.34, 70.38, 70.39, 70.42, 70.50, 70.51, 70.52, 70.53, 70.57, 70.58, 70.59, 70.61, 70.62, 70.64, 70.65, 70.72, 70.73, 70.74, and Appendix A.

* * * * *

5. The undesignated center heading ``EXEMPTIONS'' is redesignated as ``Subpart B--Exemptions.''

§§ 70.13a and 70.14 [Redesignated]

6. Sections 70.13a and 70.14 are redesignated as §§ 70.14 and 70.17, respectively.

7. The undesignated center heading “GENERAL LICENSES” is redesignated as “Subpart C--General Licenses.”

8. The undesignated center heading “LICENSE APPLICATIONS” is redesignated as “Subpart D--License Applications.”

9. The undesignated center heading “LICENSES” is redesignated as “Subpart E--Licenses.”

10. The undesignated center heading “ACQUISITION, USE AND TRANSFER OF SPECIAL NUCLEAR MATERIAL, CREDITORS' RIGHTS,” is redesignated as “Subpart F--Acquisition, Use, and Transfer of Special Nuclear Material, Creditors' Rights.”

11. The undesignated center heading “SPECIAL NUCLEAR MATERIAL CONTROL RECORDS, REPORTS AND INSPECTIONS” is redesignated as “Subpart G--Special Nuclear Material Control Records, Reports, and Inspections.”

12. In § 70.50, paragraph (c) is revised and paragraph (d) is added to read as follows.

§ 70.50 Reporting requirements.

* * * * *

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section, and by § 70.74 and Appendix A of this part, if applicable, by telephone to the NRC Operations Center.[1] To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) Caller's name, position title, and call-back telephone number;

(ii) Date, time, and exact location of the event;

(iii) Description of the event, including;

(A) Radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released;

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[1]The commercial telephone number for the NRC Operations Center is (301) 816-5100.

(B) Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from licensed materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);

(C) The sequence of occurrences leading to the event, including degradation or failure of structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and

(D) Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and reliable to perform their function.

(iv) External conditions affecting the event;

(v) Additional actions taken by the licensee in response to the event;

(vi) Status of the event (e.g., whether the event is on-going or was terminated);

(vii) Current and planned site status, including any declared emergency class;

(viii) Notifications, related to the event, that were made or are planned to any local, State, or other Federal agencies;

(ix) Status of any press releases, related to the event, that were made or are planned.

(2) Written report. Each licensee that makes a report required by paragraph (a) or (b) of this section, or by § 70.74 and Appendix A of this part, if applicable, shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the report contains all the necessary information, and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC regional office listed in Appendix D of 10 CFR Part 20. The reports must include the following:

(i) Complete applicable information required by § 70.50(c)(1);

(ii) The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(iii) Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

(iv) For licensees subject to Subpart H of this part, whether the event was identified and evaluated in the Integrated Safety Analysis.

(d) The provisions of § 70.50 do not apply to licensees subject to § 50.72. They do apply to those Part 50 licensees possessing material licensed under Part 70 that are not subject to the notification requirements in § 50.72.

13. The undesignated center heading “MODIFICATION AND REVOCATION OF LICENSES” is redesignated as “Subpart I--Modification and Revocation of Licenses.”

§§ 70.61 and 70.62 [Redesignated]

14. Sections 70.61 and 70.62 are redesignated as §§ 70.81 and 70.82, respectively.

15. The undesignated center heading “ENFORCEMENT” is redesignated as “Subpart J--Enforcement.”

§§ 70.71 [Redesignated]

16. Section 70.71 is redesignated as § 70.91.

17. Section 70.72 is redesignated as § 70.92 and paragraph (b) is revised to read as follows:

§ 70.92 Criminal Penalties

* * * * *

(b) The regulations in part 70 that are not issued under sections 161b, 161i, or 161o, for the purposes of section 223 are as follows: §§ 70.1, 70.2, 70.4, 70.5, 70.6, 70.8, 70.11, 70.12, 70.13, 70.14, 70.17, 70.18, 70.23, 70.31, 70.33, 70.34, 70.35, 70.37, 70.66, 70.73, 70.76, 70.81, 70.82, 70.63, 70.91, and 70.92.

18. In part 70, a new subpart H (§§ 70.60-70.74) is added to read as follows:

Subpart H--Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material

Sec.

70.60 Applicability.

70.61 Performance requirements.

70.62 Safety program and integrated safety analysis.

70.64 Requirements for new facilities or new processes at existing facilities.

70.65 Additional content of applications.

70.66 Additional requirements for approval of license application.

70.72 Facility changes and change process.

70.73 Renewal of licenses.

70.74 Additional reporting requirements.

70.76 Backfitting

§ 70.60 Applicability.

The regulations in § 70.61 through § 70.76 apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be: authorized to possess greater than a critical mass of special nuclear material, and engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity that the Commission determines could significantly affect public health and safety. The regulations in § 70.61 through § 70.76 do not apply to decommissioning activities performed pursuant to other applicable Commission regulations including § 70.25 and § 70.38 of this part. Also, the regulations in § 70.61 through § 70.76 do not apply to activities that are certified by the Commission pursuant to Part 76 of this chapter or licensed by the Commission pursuant to other parts of this chapter. Unless specifically addressed in § 70.61 through § 70.76, implementation by current licensees of the Subpart H requirements shall be completed no later than the time of the ISA Summary submittal required in § 70.62(c)(3)(ii).

§ 70.61 Performance requirements.

(a) Each applicant or licensee shall evaluate, in the integrated safety analysis performed in accordance with § 70.62, its compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.

(b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than those in 70.61(b)(1)-(4). High consequence events are those internally or externally initiated events that result in:

(1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to paragraph (f) of this section; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could endanger the life of a worker, or

(ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area identified pursuant to paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to § 70.65 of this part.

(c) The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both shall be applied to the extent needed so that, upon implementation of such controls, the event is unlikely or its consequences are less than those in 70.61(c)(1)-(4). Intermediate consequence events are those internally or externally initiated events that are not high consequence events, that result in:

(1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to Part 20; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could lead to irreversible or other serious, long-lasting health effects to a worker, or

(ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to § 70.65 of this part.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

(e) Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to § 70.62 of this part, shall ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.

(f) Each licensee must establish a controlled area, as defined in § 20.1003. In addition, the licensee must retain the authority to exclude or remove personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in § 70.4, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

(1) Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(2) Provides training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, and conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

§ 70.62 Safety program and integrated safety analysis.

(a) Safety program. (1) Each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. Three elements of this safety program; namely, process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.

(2) Each licensee or applicant shall establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.

(3) Each licensee or applicant shall maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or

management measure has failed to perform its function upon demand or has degraded such that the performance requirements of § 70.61 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.

(b) Process safety information. Each licensee or applicant shall maintain process safety information to enable the performance and maintenance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(c) Integrated safety analysis. (1) Each licensee or applicant shall conduct and maintain an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:

(i) Radiological hazards related to possessing or processing licensed material at its facility;

(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) Each item relied on for safety identified pursuant to § 70.61(e) of this part, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of § 70.61.

(2) Integrated safety analysis team qualifications. To assure the adequacy of the integrated safety analysis, the analysis must be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) Requirements for existing licensees. Individuals holding an NRC license on [the date of publication of the final rule] shall, with regard to existing licensed activities:

(i) By <the effective date of the final rule plus 6 months>, submit for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) By <the effective date of the final rule plus 4 years>, or in accordance with the approved plan submitted under § 70.62(c)(3)(i), complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit, for NRC approval, an integrated safety analysis summary, including a description of the management measures, in accordance with

§ 70.65 The Commission may approve a request for an alternative schedule for completing the correction of unacceptable performance deficiencies if the Commission determines that the alternative is warranted by consideration of the following:

(A) Adequate compensatory measures have been established;

(B) Whether it is technically feasible to complete the correction of the unacceptable performance deficiency within the allotted 4-year period;

(C) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis and that are beyond the control of the licensee.

(iii) Pending the correction of unacceptable performance deficiencies identified during the conduct of the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

(d) Management measures. Each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61. The measures applied to a particular engineered or administrative control or control system may be commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to § 70.61(e) of this part are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of § 70.61 of this part.

§ 70.64 Requirements for new facilities or new processes at existing facilities.

(a) Baseline design criteria. Each prospective applicant or licensee shall address the following baseline design criteria in the design of new facilities. Each existing licensee shall address the following baseline design criteria in the design of new processes at existing facilities that require a license amendment under § 70.72. The baseline design criteria must be applied to the design of new facilities and new processes, but do not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in § 70.61. Licensees shall maintain the application of these criteria unless the analysis performed pursuant to § 70.62(c) demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) Quality standards and records. The design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

(2) Natural phenomena hazards. The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) Fire protection. The design must provide for adequate protection against fires and explosions.

(4) Environmental and dynamic effects. The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) Chemical protection. The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(6) Emergency capability. The design must provide for emergency capability to maintain control of:

(i) Licensed material and hazardous chemicals produced from licensed material;

(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

(7) Utility services. The design must provide for continued operation of essential utility services.

(8) Inspection, testing, and maintenance. The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(9) Criticality control. The design must provide for criticality control including adherence to the double contingency principle.

(10) Instrumentation and controls. The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Facility and system design and facility layout must be based on defense-in-depth practices.[1] The design must incorporate, to the extent practicable:

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[1]As used in § 70.64, Requirements for new facilities or new processes at existing facilities, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through

(1) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and

(2) Features that enhance safety by reducing challenges to items relied on for safety.

§ 70.65 Additional content of applications.

(a) In addition to the contents required by § 70.22, each application must include a description of the applicant's safety program established under § 70.62.

(b) The integrated safety analysis summary must be submitted with the license or renewal application (and amendment application as necessary), but shall not be incorporated in the license. However, changes to the integrated safety analysis summary shall meet the conditions of § 70.72. The integrated safety analysis summary must contain:

(1) A general description of the site with emphasis on those factors that could affect safety (i.e., meteorology, seismology);

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to § 70.62(c)(1)(i)-(iii) and a general description of the types of accident sequences;

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performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

(4) Information that demonstrates the licensee's compliance with the performance requirements of § 70.61, including a description of the management measures; the requirements for criticality monitoring and alarms in § 70.24; and, if applicable, the requirements of § 70.64;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing each item relied on for safety which is identified pursuant to § 70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of § 70.61;

(7) A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in § 70.61(b)(4) and (c)(4);

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and

(9) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

§ 70.66 Additional requirements for approval of license application.

(a) An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied with the requirements of § 70.21, 70.22, 70.23, and 70.60 through 70.65.

(b) Submittals by existing licensees in accordance with § 70.62(c)(3)(i) will be approved if the Commission determines that:

(1) the integrated safety analysis approach is in accordance with the requirements of § 70.61, 70.62(c)(1), and 70.62(c)(2);and

(2) the schedule is in compliance with § 70.62(c)(3)(ii).

(c) Submittals by existing licensees in accordance with § 70.62(c)(3)(ii) will be approved if the Commission determines that:

(1) The requirements of § 70.65(b) are satisfied; and

(2) The performance requirements in § 70.61 (b), (c) and (d) are satisfied, based on the information in the ISA Summary, together with other information submitted to NRC or available to NRC at the licensee's site.

§ 70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (e.g., expiration date) of the change; and

(6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with § 70.62.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with § 70.34.

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change:

(1) Does not:

(i) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of § 70.61 and that have not previously been described in the integrated safety analysis summary; or

(ii) Use new processes, technologies, or control systems for which the licensee has no prior experience;

(2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary;

(3) Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and

(4) Is not otherwise prohibited by this section, license condition, or order.

(d)(1) For any changes that affect the list of items relied on for safety contained in the integrated safety analysis summary, as submitted in accordance with § 70.65, but do not require NRC pre-approval, the licensee shall submit revised pages of the integrated safety analysis summary to NRC quarterly, within 30 days after the end of the calendar year quarter during which the changes occurred.

(2) For changes that require pre-approval under § 70.72, the licensee shall submit an amendment request to the NRC in accordance with § 70.34 and § 70.65.

(3) A brief summary of all changes to the records required by § 70.62(a)(2) of this part, that are made without prior Commission approval and revised pages to the integrated safety analysis summary, must be submitted to NRC annually, within 30 days after the end of the calendar year during which the changes occurred.

(e) If a change covered by § 70.72 is made, the affected on-site documentation must be updated promptly.

(f) The licensee shall maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval under paragraph (c) or (d) of this section. These records must be maintained until termination of the license.

§ 70.73 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with §§ 2.109, 70.21, 70.22, 70.33, 70.38, and 70.65. Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

§ 70.74 Additional reporting requirements.

(a) Reports to NRC Operations Center. (1) Each licensee shall report to the NRC Operations Center the events described in Appendix A to Part 70.

(2) Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period for reporting.

(3) The information provided must include a description of the event and other related information as described in § 70.50(c)(1).

(4) Follow-up information to the reports must be provided until all information required to be reported in § 70.50(c)(1) of this part is complete.

(5) Each licensee shall provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event.

(b) Written reports. Each licensee that makes a report required by paragraph (a)(1) of this section shall submit a written follow-up report within 30 days of the initial report. The written report must contain the information as described in § 70.50(c)(2).

§ 70.76 Backfitting

(a) For each licensee, this provision shall apply to Subpart H requirements as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66. For requirements other than Subpart H, this provision applies regardless of the status of the approval of a licensee's ISA Summary.

(1) Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any

of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is an increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission finds and declares, with appropriately documented evaluation for its finding, any of the following:

(i) That a modification is necessary to bring a facility into compliance with Subpart H of this part; or

(ii) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(iii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iv) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require the backfitting of a facility if it determines that the regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section must include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediate effective regulatory action is required, then the documented evaluation may follow, rather than precede, the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written license commitments, or there are two or more ways to reach an adequate level of protection, then ordinarily the licensee is free to choose the way that best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental release of radioactive material and hazardous chemicals produced from licensed material;

(4) Potential impact on radiological exposure or exposure to hazardous chemicals produced from licensed material of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime;

(6) The potential safety impact of changes in facility or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit; and

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No license will be withheld during the pendency of backfit analyses required by the Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee.

19. Appendix A to part 70 is added to read as follows:

Appendix A to Part 70--Reportable safety events

Licensees must comply with reporting requirements in this appendix, except for (a)(1), (a)(2), and (b)(4), after they have submitted an ISA Summary in accordance with § 70.62(c)(3)(ii). Licensees must comply with (a)(1), (a)(2), and (b)(4) after (Insert 30 days after publication of this final rule). As required by 10 CFR 70.74, licensees subject to the requirements in subpart H of part 70, shall report:

(a) One hour reports. Events to be reported to the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) An inadvertent nuclear criticality.

(2) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in § 70.61(b)(4).

(4) An event or condition such that no items relied on for safety, as documented in the Integrated Safety Analysis summary, remain available and reliable, in an accident sequence evaluated in the Integrated Safety Analysis, to perform their function:

(i) In the context of the performance requirements in § 70.61(b) and § 70.61(c), or

(ii) Prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).

(5) Loss of controls such that only one item relied on for safety, as documented in the Integrated Safety Analysis summary, remains available and reliable to prevent a nuclear criticality accident, and has been in this state for greater than eight hours.

(b) Twenty-four hour reports. Events to be reported to the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the Integrated Safety Analysis, and which results in failure to meet the performance requirements of § 70.61.

(2) Loss or degradation of items relied on for safety that results in failure to meet the performance requirement of § 70.61.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of § 70.61(c)(4).

(4) Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more items relied on for safety.

(5) An occurrence of an event or process deviation that was considered in the Integrated Safety Analysis and:

(i) Was dismissed due to its likelihood; or

(ii) Was categorized as unlikely and whose associated unmitigated consequences would have exceeded those in § 70.61(b) had the item(s) relied on for safety not performed their safety function(s).

(c) Concurrent Reports. Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made, shall be reported to the NRC Operations Center concurrent to the news release or other notification.

Dated at Rockville, Maryland, this ___day of _________, 2000.

For the Nuclear Regulatory Commission.

____

Annette Vietti-Cook,

Secretary of the Commission.