

RULEMAKING ISSUE NOTATION VOTE

November 3, 2005

SECY-05-0203

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: REVISED PROPOSED RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS"

PURPOSE:

To request Commission approval to publish in the *Federal Register* revised proposed revisions to the requirements in Part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 52), "Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants," and to requirements in related sections of the regulations in Title 10 Chapter 1 which would withdraw and supersede the Commission's July 3, 2003 (68 FR 40026), proposed rule on 10 CFR Part 52.

SUMMARY:

The Nuclear Regulatory Commission (NRC) staff is proposing to amend the regulations concerning the licensing and approval processes for nuclear power plants in 10 CFR Part 52. The proposed rule contains a rewrite of 10 CFR Part 52, as well as changes throughout the Commission's regulations to enhance the NRC's regulatory effectiveness and efficiency in implementing the licensing and approval processes in Part 52 and to clarify the applicability of various requirements to each of the regulatory processes in Part 52 (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license). This rulemaking to enhance 10 CFR Part 52 is based on lessons learned during design certification and early site permit (ESP) reviews and on discussions with stakeholders about the ESP, design certification, and combined license (COL) review processes.

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On July 3, 2003 (68 FR 40026), the NRC published a proposed rule to clarify the NRC's regulations related to nuclear power plant licensing under Part 52. Upon further consideration, the staff is proposing to amend the requirements for the licensing and approval processes in the regulations that will withdraw and supersede the 2003 proposed rule. The staff believes that this new rulemaking action will improve the effectiveness and efficiency of the licensing and approval processes in Part 52 for future applicants.

BACKGROUND:

The NRC staff planned to update 10 CFR Part 52 after the first standard design certification reviews. The proposed rulemaking action began with the issuance of SECY-98-282, "Part 52 Rulemaking Plan," on December 4, 1998 (ML032801416). The Commission issued a staff requirements memorandum on January 14, 1999 (ML032801439), approving the NRC staff's plan for revising 10 CFR Part 52. Subsequently, the NRC staff obtained considerable stakeholder comment on its planned action. On July 3, 2003 (68 FR 40026), the NRC published a proposed rule that would clarify miscellaneous parts of the NRC's regulations; update 10 CFR Part 52 in its entirety; and incorporate stakeholder comments.

Following the close of the public comment period on the July 2003 proposed rule, a number of factors led the staff to question whether that proposed rule would meet the Commission's objective of improving the effectiveness of NRC's processes for licensing future nuclear power plants. First, public comments identified several concerns about whether the proposed rule adequately addressed the relationship between Part 50 and Part 52 and clearly specified the applicable regulatory requirements for each of the licensing and approval processes in Part 52. In addition, as a result of the staff's review of the first three ESP applications, the staff gained additional insights into the ESP process. The staff also had the benefit of public meetings with external stakeholders on the development of staff guidance on the ESP and COL processes. As a result, the staff decided that a substantial rewrite and expansion of the original proposed rulemaking to include changes throughout the entire body of NRC regulations in Title 10 Chapter 1 was desirable so that the agency may more effectively and efficiently implement the licensing and approval processes for nuclear power plants in Part 52. The staff again considered previously submitted comments in developing this proposed rule and, on August 25, 2005, posted draft rule language on the rulemaking Web site and published a notice of the availability of the draft rule language in the *Federal Register* (September 6, 2005; 70 FR 52942).

DISCUSSION:

As discussed in the attached *Federal Register* notice, the revised proposed rule contains a rewrite of Part 52, as well as changes throughout the NRC's regulations, to improve the organization, format, and language of Part 52 and to clarify the applicability of various technical and regulatory requirements throughout Title 10 Chapter 1 to each of the processes in Part 52. In light of the substantial rewrite of the July 2003 proposed rule, the expansion of the scope of the rulemaking, and the staff's recommendation to publish the revised proposed rule for public comment, the staff has decided that developing responses to comments received on the 2003 proposed rule is not an effective use of agency resources. The staff recommends that commenters on the 2003 proposed rule who believe that their earlier comments are not addressed in the revised proposed rule (or are not adequately addressed) resubmit their

comments. The staff will provide resolutions for comments received on the revised proposed rule in the statement of considerations for the final rule.

Since the Commission first adopted 10 CFR Part 52 in 1989, the NRC and external stakeholders have identified a number of interrelated issues and concerns. The fundamental concern is that the overall regulatory relationship between Part 50 and Part 52 is not always clear, and it is often difficult to tell whether general regulatory provisions in Part 50 apply to Part 52. A related concern is the current lack of specific delineation of the applicability of NRC requirements throughout Title 10 Chapter 1 to the licensing and approval processes in Part 52. For example, the indemnity and insurance provisions in Part 140 were not revised to address their applicability to applicants for and holders of COLs under Subpart C of Part 52. Even where Part 52 provisions referenced specific requirements in Part 50, it was not always clear from the language of the Part 50 requirements how the requirements applied to the Part 52 processes. For example, current § 52.47(a)(1)(i) provides that a standard design certification application must contain the “technical information which is required of applicants for construction permits and operating licenses by 10 CFR...part 50...and which is technically relevant to the design and not site-specific.” The language does not explicitly identify the Part 50 requirements that are “technically relevant to the design.” Even where a specific regulation in Part 50 is identified as a requirement, the language of the referenced regulation itself was not changed to reflect that the specific requirements applied to the Part 52 processes. For example, § 52.79(b) provides that the application must contain the “technically relevant information required of applicants for an operating license required by 10 CFR 50.34.” Further, § 50.34(b) is based upon the two-step licensing process whereby certain important information is submitted at the construction permit (CP) stage and then supplemented with more detailed information at the operating license stage. Thus, information that must be submitted in the CP application (e.g., the “principal design criteria for the facility” required by § 50.34(a)(3)(i)), may be regarded as not required to be submitted for a COL application under the current version of Part 52.

In the 2003 proposed rule, the NRC proposed several changes that were intended to address some (but not all) of these issues. However, based on comments received on the 2003 proposed rule, the NRC’s experience to date with ESP applications, interactions with external stakeholders concerning NRC regulatory guidance for COL applications, and the NRC’s screening of Title 10 Chapter 1 requirements following the receipt of public comments on the 2003 proposed rule, the staff concludes that the 2003 proposed rule would not adequately address and resolve these issues. Accordingly, the staff now proposes to take a more comprehensive approach to addressing these issues by reorganizing Part 52, implementing a uniform format and content for each of the subparts in Part 52, using consistent wording and organization of sections in each of the subparts, and making conforming changes throughout Title 10 Chapter 1 to reflect the licensing and approval processes in Part 52. The staff has also attempted to coordinate and reconcile differences in wording among provisions in Parts 2, 50, 51, and 52 to provide consistent terminology throughout the regulations affecting Part 52.

Under the NRC’s proposed reorganization of Part 52, the existing Appendices O and M on standard design approvals and manufacturing licenses, respectively, would be redesignated as new subparts in Part 52. Redesignating these appendices as subparts in Part 52 would result in a consistent format and organization of the requirements applicable to each of the licensing and approval processes in Part 52. In addition, the redesignation would clarify that each of the licensing and approval processes in these appendices are available to potential applicants as

an alternative to the licensing and approval processes in Part 50 (construction permit and operating license) and the existing subparts A through C of Part 52. By doing so, the staff is simply attempting to standardize the format and organization of Part 52, and to clarify the full range of licensing and regulatory alternatives that are available under Part 52 for use by potential applicants. Consistent with the broad scope of Part 52, the NRC proposes to retitle 10 CFR Part 52 as "Licenses, Certifications, and Approvals for Nuclear Power Plants." The staff's proposed revision to Part 52 will contain five subparts: one each for ESPs (Subpart A), design certifications (Subpart B), COLs (Subpart C), design approvals (Subpart E), and manufacturing licenses (Subpart F). The staff proposes to reserve Subpart D for possible future use.

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

Appendix N, which addresses duplicate design licenses, will be removed from Part 52 and will be retained in Part 50, because the duplicate design license is a Part 50 operating license. Appendix Q, which addresses early staff review of site suitability issues, will also be removed from Part 52 but retained in Part 50. Appendix Q provides for NRC staff issuance of a staff site report on site suitability issues with respect to a specific site for which a potential applicant seeks the NRC staff's views. This early site review process is separate from the ESP process in Subpart A of Part 52. The staff recognizes that there appears to be some redundancy between the early site review process and the ESP process. Accordingly, the staff proposes to remove Appendix Q from Part 52 and retain it only in Part 50.

The staff has reviewed the existing regulations in Title 10 Chapter 1 to determine if they must be modified to reflect the licensing and approval processes in Part 52. This review had two aspects. First, the staff determined whether an existing regulatory provision must, by virtue of a statutory requirement or regulatory necessity, be extended to address a Part 52 process and, if so, how the regulatory provision should apply. Second, in situations where the Commission has some discretion, the staff determined whether there were policy or regulatory reasons to extend the existing regulations to each of the Part 52 processes. Most of the NRC's proposed conforming changes occur in 10 CFR Part 50. In making changes involving 10 CFR Part 50 provisions, the staff adopted the general principle of keeping the technical requirements in 10 CFR Part 50 and maintaining all applicable procedural requirements in 10 CFR Part 52. However, due to the complexity of some provisions in 10 CFR Part 50 (e.g., § 50.34), this principle could not be universally followed. A description of, and bases for, the proposed conforming changes are discussed in the attached *Federal Register* notice for each affected part. Because of the expanded nature of the revised proposed rulemaking, the staff prepared an updated regulatory analysis which is provided as an attachment to this paper (Attachment 2).

The staff recently sent another paper to the Commission, SECY-05-120, "Security Design Expectations for New Reactor Licensing Activities," (ML051100233) recommending changes to

requirements for new reactors in the area of security. In its staff requirements memorandum for SECY-05-120, dated September 9, 2005 (ML052520334), the Commission approved the staff's recommendations to require applicants to submit a safety and security assessment addressing the relevant security requirements which were established for currently operating plants by order,¹ including the requirements for protection against the supplemented design-basis threat and the requirements for enhanced mitigative measures. The staff's implementation of these recommendations will be addressed in a future rulemaking.

The following discussion highlights several staff proposals in the revised proposed rulemaking for Commission consideration:

- Segregation of the Part 50 and Part 52 licensing processes
- Reform of the manufacturing license process
- Emergency preparedness requirements for ESP applicants and COL holders
- Issues affecting ESP finality
- Quality assurance requirements for ESP applicants
- Applicability of 10 CFR Part 21 and 10 CFR 50.55(e)
- Probabilistic Risk Assessment (PRA) requirements

In addition, discussions on three additional issues can be found in SECY-02-0077, "Proposed Rule to Update 10 CFR Part 52, Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants" (ML021050284). The first issue relates to the Commission's direction in 1994 to impose requirements on future licensees to maintain, update, and use a PRA for the life of a nuclear facility. In SECY-02-0077, the staff stated that it is not necessary in today's regulatory environment to impose requirements that licensees maintain, update, and use a PRA for the life of the facility (i.e., a living PRA). The staff now intends to consider the need for a living PRA as part of its program plan to make risk-informed performance-based revisions to 10 CFR Part 50. Therefore, the staff is not proposing to add a living PRA requirement to 10 CFR Part 52. The second issue discussed in SECY-02-0077 relates to a nuclear industry proposal in 1999 to revise the change criteria in the design certification rule. The third issue is the status of two petitions submitted by the Nuclear Energy Institute (NEI) to revise the requirements in 10 CFR Part 52.

This revised proposed rule retains the changes originally proposed in SECY-02-0077 to resolve these first two issues, with one addition to the PRA requirements as discussed later in this paper. In addition, both the 2003 proposed rule and this revised proposed rule address the Commission's disposition of one of the two NEI petitions (PRM 52-2) discussed in SECY-02-0077.² Resolution of the second petition did not result in any changes to the regulations. Proposals related to the remaining two issues discussed in SECY-02-0077 have

¹ February 25, 2002, All Operating Reactor Licensees, Order Modifying License (Effective Immediately), EA-02-26, 67 FR 9792 (March 4, 2002); April 29, 2003, All Operating Reactor Licensees, Order Modifying License (Effective Immediately), EA-03-086, 68 FR 24,517 (May 7, 2003).

² The staff discussed its proposed resolution of PRM 52-2 in SECY-02-0175 (September 27, 2002) and of PRM 51-1 in SECY-02-0199 (November 8, 2002).

been revised in this proposed rule and are discussed below (emergency preparedness requirements and the applicability of Part 21).

Segregation of Part 50 and Part 52 Licensing Processes

Currently, Part 52 allows an applicant for a CP to reference either an ESP under Subpart A or a design certification under Subpart B. The staff proposes that the Commission seek stakeholder feedback on whether the provisions allowing a CP applicant to reference an ESP or a design certification should be removed entirely from 10 CFR Part 52. The staff believes that removing these provisions will ensure the most effective use of agency resources for new reactor licensing activities. The current regulations in 10 CFR Part 50 that address the application for and granting of CPs do not address a CP applicant's ability to reference either an ESP or a design certification and the staff has not developed any guidance on how the CP process would incorporate an ESP or design certification. In addition, the staff proposes that future applicants who want to construct and operate a commercial nuclear power facility use the COL process in Subpart C of Part 52.

Reform of Manufacturing License Process

Appendix M of Part 52 sets forth the Commission's requirements governing manufacturing licenses. Appendix M, which was first adopted by the Commission in 1973, provides for issuance of a license authorizing the manufacture of a nuclear power reactor to be incorporated into a nuclear power plant under a CP and operated under an operating license at a different location from the place of manufacture. Under the current licensing regime in Appendix M, the Commission does not approve a final reactor design to be manufactured prior to issuance of the manufacturing license. Rather, analogous to the two-step process, the Commission issues a manufacturing license based upon the review of a preliminary design equivalent to the design information that is provided in a CP application. Upon approval of the preliminary design and associated information, the Commission issues a manufacturing license authorizing the manufacture—but not the removal from the manufacturing site—of one or more nuclear power reactors. Thereafter, manufacturing can commence, although the Commission must approve the final design of the manufactured reactor by license amendment (see the note in paragraph 7 of Appendix M). Under paragraph 8 of Appendix M, the manufactured reactor may not be removed from the place of manufacture until approval of the final design under paragraph 7.

In view of the substantial reorganization and rewriting of Title 10 Chapter 1 the staff has reconsidered the efficacy of the current manufacturing license process in Appendix M and proposes substantial changes to enhance regulatory effectiveness and efficiency. The most important change is that a final reactor design, equivalent to that required for a standard design certification under Part 52 or an operating license under Part 50, must be submitted and approved before issuance of a manufacturing license. There are several reasons for this change. First, the staff's experience with standard design certifications demonstrates that nuclear power plant designers are technically capable of developing a final reactor design for Commission review and approval. Second, approval of a final reactor design removes the current awkward regulatory process of issuing a manufacturing license and then amending the license when a final design is submitted. Approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the actual manufacture of the reactor, which will enhance regulatory stability

and reduce financial risk. Finally, Commission approval of standardized manufacturing processes, by promoting workforce stability and manufacturing process feedback, will help maintain and possibly greatly improve the quality and standardization of the manufactured reactors, compared to the traditional construction of reactors on site by numerous contractors and subcontractors.

The proposed requirements for a manufacturing license set forth in proposed Subpart F of Part 52 reflect both the expanded scope of approval to include the final design of the reactor to be manufactured and the lessons learned from the ESP application reviews. Also, in light of the staff's proposal to provide approval of a final design in a manufacturing license, the staff proposes to provide a greater degree of finality for a manufacturing license, comparable to the finality provided for standard design certifications.

Emergency Preparedness

Issues regarding the review and verification of emergency preparedness for nuclear power plants have been the subject of much correspondence between the NRC staff and Commission from 1989 to the present. In preparing the 2003 proposed rule, the staff reviewed the historical record of the requirements for emergency preparedness exercises for COL holders and evaluated whether proposed changes to 10 CFR Part 52 were necessary. SECY-02-0077 contains a summary of the staff's review of the history of this issue. The staff confirmed that a full-participation exercise need not be performed before issuance of a COL. In SECY-02-0077, the staff stated that it had determined that the requirements in 10 CFR Part 52 related to emergency preparedness exercises did not need to be revised, but that the emergency planning regulations in 10 CFR Part 50 needed to be amended in order to incorporate the existing licensing processes in 10 CFR Part 52 for ESPs and COLs. At that time, the staff planned to include conforming administrative changes to 10 CFR Part 50, Appendix E, with an upcoming rulemaking that was outlined in SECY-01-0131, "Rulemaking Plan: Revision of Appendix E, Section IV.F.2, to 10 CFR Part 50, Concerning Clarification of Emergency Preparedness Exercise Participation Requirements of Co-Located Licensees" (ML011520066).

When the staff began to prepare this revised proposed rule, the conforming changes to Part 50, Appendix E, were not complete. The staff decided to include those changes in this Part 52 rulemaking because the staff had expanded the scope of the Part 52 rulemaking to include conforming changes to Part 50. The major proposed changes regarding emergency preparedness requirements for ESP and COL applicants are provided below.

Emergency Preparedness Requirements for Early Site Permit Applicants

The staff proposes to amend Part 52 to address changes to emergency preparedness requirements for ESP applicants. The staff proposes to amend § 52.17(b)(1), which requires that an ESP application identify physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans. The staff proposes to add a sentence stating that if physical characteristics that could pose a significant impediment to the development of emergency plans are identified, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. The staff believes this addition is necessary to clarify the staff's expectations in cases where a physical characteristic exists that could pose a significant impediment to the development of emergency

plans. Identification of such physical characteristics does not provide the staff with sufficient information to determine if such characteristics are likely to pose a significant impediment to the development of emergency plans.

The staff also proposes to add new provisions in § 52.17 to require that complete and integrated emergency plans submitted for review in an ESP application must include the proposed inspections, tests, and analyses that the holder of a COL referencing the ESP must perform and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC's regulations. The staff is proposing these amendments because it believes that its review of complete and integrated plans included in an ESP application should be no different than its review of emergency plans submitted in a COL application given that the Commission must make the same findings in both cases, namely, that the plans submitted by the applicant provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The Commission will not be able to make the required finding in the absence of proposed inspections, tests, analyses, and acceptance criteria (ITAAC) in an ESP application that includes complete and integrated emergency plans. Also, requiring the inclusion of emergency preparedness ITAAC in the ESP application is consistent with the Commission's goal of resolving siting issues early in the licensing process. Therefore, the staff proposes to require that ESP applicants that submit complete and integrated emergency plans at the ESP stage also be required to include emergency preparedness ITAAC in their ESP application.

Emergency Preparedness Exercise Requirements for COL Holders

Section 50.47 and Appendix E to 10 CFR Part 50 contain emergency planning requirements for nuclear power plants. Because these regulations do not clearly specify their applicability to ESP or COL applicants or holders, the staff is proposing to make a number of clarifying changes in these regulations. Proposed changes related to the conduct of emergency preparedness exercises are discussed below.

The staff proposes modifying Section IV of Appendix E, "Content of Emergency Plans," to require that, for a COL, the first full-participation exercise be conducted within 2 years of the scheduled date for initial loading of fuel and that if the first full-participation exercise is conducted more than 1 year prior to the scheduled date for initial loading of fuel, an exercise which tests the licensee's onsite emergency plans must be conducted no more than 1 year before the scheduled date for initial loading of fuel. These requirements are analogous to those for the operating license process, taking into account the differences in the COL licensing process.

The staff is also proposing changes in § 50.47. Section 50.47(d) currently provides that no NRC or Federal Emergency Management Agency (FEMA) review, findings, or determinations concerning the state of offsite emergency preparedness or the adequacy of and capability to implement State, local, or utility offsite emergency plans are required prior to issuance of an operating license authorizing only fuel loading or low-power testing and training (up to 5 percent of the rated power) provided the NRC makes a finding that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will

be taken in the event of a radiological emergency. Providing parallel provisions to § 50.47(d) for COL holders has proven complicated. To do so, the staff has proposed to add a new § 50.47(e), and because of the nature of the COL process, the staff has also proposed a coordinated revision to § 50.54, "Conditions of licenses," to provide a condition to be added to all COLs allowing operation at up to 5 percent power with deficiencies identified by FEMA. This is necessary to account for the fact that the COL will already be issued at the time of the first full- or partial-participation exercise and that it will contain ITAAC requiring that there be no offsite emergency preparedness deficiencies.

Although the staff believes that the regulatory scheme provided by its proposed revisions to the emergency preparedness requirements in 10 CFR Part 50 is consistent with the current operating license process, the staff is concerned that allowing COL holders to operate at up to 5 percent power with offsite emergency preparedness deficiencies could result in consequent contamination of the reactor with no assurance that the plant will ever operate at full power. The staff will consider this issue as part of its overall review of the emergency preparedness regulations in accordance with the Commission's December 20, 2004 Staff Requirements Memorandum on the Briefing on Emergency Preparedness Program Initiatives (ML043550354).

The staff also proposes to add new requirements to Appendix E to Part 50 that, if the applicant has an operating reactor at the site, an exercise, either full- or partial-participation, be conducted for each subsequent reactor constructed on the site. This new provision is desirable because of the nature of ITAAC for emergency preparedness requirements. The emergency preparedness ITAAC, specifically ITAAC that will be demonstrated through an exercise, provide the necessary reasonable assurance for programs and facilities associated with the yet-unbuilt reactor. Recent agreements between the NRC and external stakeholders on emergency preparedness ITAAC are based on the understanding that ITAAC for the emergency preparedness exercise will demonstrate various aspects of emergency preparedness (e.g., programs and facilities) that do not need specific, detailed ITAAC. For example, there is no ITAAC for determining whether an adequate staffing roster exists for the technical support center or emergency operations facility, but the adequacy of staffing could be demonstrated during an exercise. Therefore, Appendix E requirements for emergency preparedness exercises must be included for the current concepts of emergency preparedness ITAAC to be valid. With regard to subsequent reactors, those aspects of an exercise which address currently untested (i.e., unexercised) aspects of emergency preparedness for the proposed new reactor must be addressed in new emergency preparedness ITAAC. If various generic exercise-related elements of emergency preparedness for the site have been previously addressed and satisfied, no ITAAC will be required for those elements of emergency preparedness for subsequent reactors.

Issues Affecting ESP Finality

Emergency Preparedness Requirements for a COL Applicant Referencing an Early Site Permit

The staff proposes to modify §§ 52.39 and 52.79 to require a license applicant referencing an ESP to update and correct the emergency preparedness information provided under § 52.17(b). The issue of updating an ESP was first raised by the Illinois Department of Nuclear Safety, which suggested in a September 28, 1994, letter that emergency plans and/or offsite

certifications approved as part of an ESP review be kept up to date throughout the duration of an ESP and the construction phase of a COL.

The staff agrees in part with the Illinois Department of Nuclear Safety. However, the staff believes that there is no need to update the emergency plans approved in an ESP until the permit is referenced in a COL or CP application. At that time, the emergency plans will have to be reviewed to confirm that they are up to date and to provide new information that may materially affect the Commission's earlier determination on emergency preparedness or that is needed to correct inaccuracies in the emergency preparedness information approved in the ESP to support a reasonable assurance determination. Accordingly, the staff is proposing that §§ 52.39 and 52.79 contain an updating requirement to be imposed upon the applicant referencing an ESP.

In addition, the staff is proposing that the applicant must discuss whether the new information could materially change the bases for compliance with the applicable NRC requirements. New information which materially changes the bases for compliance includes (1) information which substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan and (2) information which constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness in accordance with § 52.39(a)(1). New information which materially changes the Commission's determination on emergency preparedness matters or results in modifications of existing terms and conditions of the ESP will be subject to litigation during the CP or COL proceedings in accordance with § 52.39(c).

In a related matter, the staff proposes to accord finality to changes to an ESP emergency plan (or major features thereof) that are made after the issuance of the ESP if (1) the approved ESP emergency plan (or major feature) is based upon an emergency plan in use by a licensee of a nuclear power plant; (2) the changes to the ESP emergency plan are identical to the changes in the referenced licensee's plan; and (3) the changes in the referenced licensee's emergency plan are in compliance with § 50.54(q). The staff's proposal is based on the position that changes to emergency plans which are properly implemented under § 50.54(q) do not require NRC review and approval before implementation; therefore similar changes to an ESP's emergency preparedness plan made under similar controls should not require NRC review and approval as part of the new licensing process.

Requirements for Staff Review of New and Significant Environmental Information at the COL Stage

Currently, 10 CFR Part 51 does not reference the Part 52 licensing and approval processes. The staff is proposing conforming changes to Part 51 to address this lack of specific reference. One of the proposals has been the subject of much discussion between the NRC staff and nuclear industry stakeholders, namely, the staff's proposal to add a requirement in § 51.50 that the applicant's environmental report for a COL application referencing an ESP must contain any new and significant information on the site or design to the extent that the information differs from, or is in addition to, the information discussed in the ESP environmental impact statement (EIS). The staff is also proposing to add a requirement that the applicant must have an acceptable process for identifying any new and significant information regarding the NRC's conclusions in the ESP EIS.

The NRC's regulations and the applicable case law interpreting the National Environment Policy Act of 1969 (NEPA), as amended, support the staff's belief that, inasmuch as an ESP and a COL are major Federal actions significantly affecting the quality of the human environment, both actions require the preparation of an EIS. However, 10 CFR Part 52 provides finality for previously resolved issues. Under NEPA, the COL environmental review is informed by the EIS prepared at the ESP stage, and the NRC staff intends to use tiering and incorporation by reference whenever it is appropriate to do so. The COL applicant must address any other significant environmental issues not considered in any previous proceeding, such as issues deferred from the ESP stage to the COL stage (e.g., the benefits assessment).

For an ESP, the NRC prepares an EIS that resolves numerous issues within certain bounding conditions. These issues are candidates for issue preclusion at the COL, CP, or operating license stage. While the NRC is ultimately responsible for completing any required NEPA review, including ensuring that the conclusions for a resolved ESP environmental issue remain valid for a COL action, the NRC staff proposes that a COL applicant must identify whether there is new and significant information on the issue. A COL applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form for issues for which the COL applicant does not identify any new and significant information. The NRC will independently evaluate and be responsible for the reliability of all information used in the EIS prepared for a COL. In carrying out its responsibilities, the staff may (1) inquire into the continued validity of information disclosed in an EIS for an ESP that is referenced in a COL application and (2) look for any new information that may affect the assumptions, analysis, or conclusions in the ESP EIS.

In conclusion, the NRC staff has determined that the issuance of a COL is a major Federal action significantly affecting the quality of the human environment and, in accordance with 10 CFR 51.20, the NRC must prepare an EIS for the action. For matters resolved at the ESP stage, if there is no new and significant information that materially differs from that discussed in the ESP EIS, then the staff will rely upon ("tier off") the ESP EIS and disclose the NRC conclusion for matters covered in the ESP review. Such matters will not be subject to litigation at the COL stage.

Revision to the ESP Finality Provisions

The staff proposes to make changes to § 52.39 to address the finality of an ESP. With the benefit of hindsight and experience gained in reviewing the first three ESP applications and recognizing the industry's preference to provide less detail in an ESP application than was originally envisioned by the Commission, the staff believes that most issues concerning a referenced ESP may be characterized as:

- (1) Questions about whether the site characteristics, design parameters, or terms and conditions specified in the ESP have been met;
- (2) Significant new emergency preparedness or environmental information not considered for the ESP; or

- (3) Questions regarding whether the early site permit should be modified, suspended, or revoked.

Questions about whether the referencing application demonstrates compliance with the ESP are fundamentally questions of compliance with the ESP. Such compliance matters are specific to the proceeding for the referencing application, and the staff concludes that such matters about whether the referencing application complies with the ESP should be regarded as questions material to the proceeding and admissible as contentions in the referencing application proceeding if the usual requirements for timely admitted contentions in 10 CFR Part 2 are met.

The staff also regards new emergency preparedness information submitted in the referencing application which materially changes the Commission's determination on emergency preparedness matters as an issue material to the proceeding and admissible as a contention in the referencing application proceeding. Likewise, any significant environmental issue not considered for the ESP is also subject to litigation during the proceeding on the referencing application to the extent the issue differs from issues discussed or reflects significant new information. Because new emergency preparedness or environmental information will be identified only at the time a license application referencing the early site permit is submitted to the NRC, the staff believes it is appropriate to address such issues in the proceeding on the referencing application.

Other questions regarding whether the permit should be modified, suspended, or revoked equate to challenges to the validity of the ESP. The Commission's process for challenges to the validity of a license is given in 10 CFR 2.206. Accordingly, the staff concludes that challenges to the validity of an ESP should be processed in accordance with § 2.206.

OGC has advised the staff that other alternatives are available that would provide for the updating of emergency preparedness and environmental information to occur outside of the referencing COL proceeding. The staff does not consider the alternatives to be an efficient or effective use of agency resources, especially in light of the manner in which early site permit applicants have chosen to pursue an early site permit (e.g., use of a plant parameter envelope), deferring resolution of many issues until the COL stage. The staff believes it is most efficient to expend resources to update early site permit issues only when the early site permit is referenced in a COL application and to address early site permit updating issues in the COL proceeding, as opposed to updating the early site permit in a proceeding separate from the COL proceeding. Under this approach, all issues affecting the COL are addressed in one proceeding.

QA Requirements for ESP Applicants

The subject of quality assurance requirements for the first three ESP applications (submitted in late 2003) was addressed in an NRC letter to Mr. Ronald Simard of the Nuclear Energy Institute on February 3, 2003 (ML030160555). In that letter, the NRC staff stated that the current regulations in 10 CFR Part 52 did not require that a 10 CFR Part 50, Appendix B, program be implemented in support of ESP applications. However, the staff further stated that ESP activities associated with site safety must be controlled by QA measures sufficient to provide reasonable assurance that future safety-related systems, structures, and components (SSCs) of a nuclear power plant or plants that might be constructed on the site will perform adequately.

Implementation of this guidance for the first three ESP applications proved challenging and the staff believes that future ESP reviews will be significantly improved by the addition of an explicit QA requirement for ESP applicants.

With certain exceptions, the regulations in § 52.39 require the Commission to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a CP, operating license, or COL. Because of this finality, conclusions made during the ESP phase will be relied upon for use in subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an ESP is issued. Therefore, the staff believes that the level of quality used to control activities related to safety-related SSCs should be equivalent in the ESP and COL phases. Applicants must apply quality controls to each ESP activity associated with the generation of design information for safety-related SSCs that meet the criteria in Appendix B. Therefore, the staff proposes to modify 10 CFR 50.55(f), Appendix B, and § 52.17 to make these QA requirements applicable to ESPs.

Applicability of 10 CFR Part 21 and 10 CFR 50.55(e)

The proposed rule includes a number of conforming changes to clarify the applicability of 10 CFR Part 21 and equivalent requirements in 10 CFR 50.55(e) to individuals, corporations, partnerships, or other entities doing business within the United States (as well as directors and responsible officers of such organizations), that hold a permit or license under 10 CFR Part 52. These conforming changes will address an omission in the existing regulations and ensure that the requirements in 10 CFR Part 21 or § 50.55(e) apply to applicants for and holders of ESPs, design approvals, design certifications, COLs, and manufacturing licenses and suppliers of basic components to such applicants or holders. Note that the staff's current proposals regarding the applicability of Part 21 or § 50.55(e) to applicants for and holders of ESPs and design certifications are different from the staff's positions in the 2003 proposed rulemaking. The changes are mainly the result of the staff's experience in reviewing ESPs and design certification applications since the earlier proposed rule was developed.

The staff's proposal is based on the belief that the extension of NRC's reporting requirements implementing Section 206 to Part 52 licensing and approval processes should be consistent with three key principles. First, NRC regulatory requirements implementing Section 206 should be a legal obligation throughout the entire "regulatory life" of a NRC license, standard design approval, or standard design certification. Second, defects should be reported whenever the information on potential defects will be most effective in ensuring the integrity and adequacy of the NRC's regulatory activities under Part 52 and the activities of entities subject to the Part 52 regulatory regime.³ Third, each entity conducting activities within the scope of Part 52 should develop and implement procedures and practices to ensure that it accurately and timely fulfills its Section 206 reporting obligations. The application of these three principles to each of the Part 52 licensing and approval processes is described in detail in the attached *Federal Register* notice.

³Throughout this discussion, reference to entities, licensees, and/or applicants includes the contractors and subcontractors of those entities, licensees, and/or applicants.

Section 50.55(e) addresses the obligation of holders of CPs and their contractors and subcontractors to report defects constituting a substantial safety hazard. These requirements, which implement Section 206 of the Energy Reorganization Act (ERA) of 1974, as amended, are comparable to the requirements set forth in 10 CFR Part 21. The staff proposes to retain the current regulatory structure, whereby persons and entities engaged in construction activities (and their contractors and subcontractors) are subject to § 50.55(e), and persons and licensees who are authorized to operate a nuclear power plant (and their contractors and subcontractors) are subject to Part 21. Inasmuch as a COL under Part 52 authorizes both construction and operation, a COL holder is subject to the reporting requirements in § 50.55(e) from the date of issuance of the COL until the date that the Commission makes the finding under § 52.103(g). Thereafter, the COL holder will be governed by the reporting requirements in Part 21. The manufacture of a nuclear power reactor under a manufacturing license is the functional equivalent of construction (though only for the reactor, not for the entire facility as in the case of a CP or COL). Accordingly, the staff's view is that the holder of a manufacturing license should be subject to reporting under § 50.55(e). ESPs precede construction and are considered partial CPs; hence the staff believes that they should be subject to reporting under § 50.55(e). Standard design approvals under proposed Subpart E and design certifications under Subpart B of Part 52 are not directly associated with construction, and the staff believes that their reporting should be addressed under Part 21.

Probabilistic Risk Assessment Requirements

The revised proposed rule amends the requirement in proposed § 52.47(b)(1) for a design-specific PRA to clarify that the PRA must be full scope and account for all modes of plant operation (including shutdown) and initiating events. This proposed clarification is intended to indicate that the PRA submitted in a design certification application must be a full-scope PRA that comprises three sequential levels, including an evaluation of core damage frequency, followed by an evaluation of accident releases, and ending with an evaluation of radiological consequences. In addition, the PRA must account for internal events (e.g., loss-of-coolant accident and loss of offsite power) and external events (e.g., flooding, seismic events, and fire) for all modes of plant operation. The staff is proposing this clarification to provide additional guidance to applicants on the scope of the PRA that must be submitted with the design certification application.

Similarly, the staff is proposing changes to current § 52.79(b) (proposed § 52.80(a)), proposed § 52.137, and proposed § 52.158 to require that applications contain a PRA. This amendment would require that if an application for a COL references a standard design certification or standard design approval or if the application proposes to use a nuclear power reactor manufactured pursuant to a manufacturing license under Subpart F of Part 52, the plant-specific PRA must use the PRA for the design certification, design approval, or manufactured reactor, as applicable, and must be updated to account for site-specific design information and any design changes, departures, or variances. The staff also proposes to include a requirement that a COL application that does not reference a certified design, design approval, or manufactured reactor must contain a plant-specific PRA. Like the requirements for a design certification applicant, the proposed § 52.80(a) requires that the plant-specific PRA be full scope and account for the operating modes and initiating events. The *Federal Register* notice states that the initiating events addressed should include internal and external events that account for site-specific characteristics.

In summary, the staff recommends that the Commission approve issuance of the attached revised notice of proposed rulemaking for public comment that will withdraw and supersede the July 2003 notice of proposed rulemaking.

RECOMMENDATION:

That the Commission:

1. Approve withdrawal of the previously published proposed rule and publication of the attached revised notice of proposed rulemaking.
2. Certify that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities in order to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. Note—
 - a. The rulemaking will be published in the *Federal Register* with a 75-day public comment period.
 - b. This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule will be submitted to the Office of Management and Budget (OMB) for review and approval of the paperwork requirements.
 - c. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for the certification, as required by the Regulatory Flexibility Act.
 - d. The appropriate congressional committees will be informed.

RESOURCES:

In the fiscal year (FY) 2007 budget submission, the staff estimated 1.3 FTE in FY 2006 to complete the rulemaking. Based on the current status of this rulemaking, the staff now estimates a total of 1.5 FTE in FY 2006 (1.0 FTE for the Office of Nuclear Reactor Regulation (NRR), 0.3 FTE for OGC, and 0.2 for the Office of Nuclear Security and Incident Response (NSIR)) and 0.6 FTE in FY 2007 (0.5 FTE for NRR and 0.1 FTE for OGC). These resources have been included in the budgets for NRR, NSIR, and OGC for FY 2006 and FY 2007.

COORDINATION:

The staff provided the Advisory Committee on Reactor Safeguards (ACRS) with a draft proposed rulemaking package for 10 CFR Part 52 on August 10, 2005. In a letter dated September 20, 2005, the ACRS stated that it planned to review the draft final version of the rulemaking following the reconciliation of public comments. The Committee To Review Generic Requirements will also review the draft final version of the rulemaking following the reconciliation of public comments.

The Office of the General Counsel has no legal objection to this paper. The Chief Financial Officer concurs in the proposed changes to 10 CFR Part 170. The Office of the Chief Financial Officer has also reviewed this paper for resource implications and has no objections. In addition, the Office of Nuclear Security and Incident Response coordinated offsite emergency preparedness related changes with the Department of Homeland Security/Federal Emergency Management Agency.

/RA Martin J. Virgilio Acting For/

Luis A. Reyes
Executive Director
for Operations

Attachments: 1. *Federal Register* Notice
2. Regulatory Analysis

NUCLEAR REGULATORY COMMISSION

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

RIN 3150 - AG24

Licenses, Certifications, and Approvals for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations by revising the provisions applicable to the licensing and approval processes for nuclear power plants and making necessary conforming amendments throughout the NRC's regulations to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. The proposed changes would clarify the applicability of various requirements to each of the licensing processes (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license). On July 3, 2003 (68 FR 40026), the NRC published a proposed rulemaking to clarify and correct the NRC's regulations related to nuclear power plant licensing. Upon further consideration, the NRC is now proposing to withdraw the 2003 proposed rule, and is proposing new requirements to enhance its licensing and approval processes and changes throughout the NRC's regulations to support these processes. The Commission believes that this rulemaking action will improve the effectiveness and efficiency of the licensing and approval processes for future applicants.

DATE: Submit comments by [insert date 75 days after publication in the Federal Register.]

Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please

include the following number (RIN 3150-AG24) in the subject line of your comments.

Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1966. You may also submit comments via the NRC's rulemaking web site at <http://ruleforum.llnl.gov>. Address questions about our rulemaking website to Carol Gallagher 301-415-5905; e-mail cag@nrc.gov. Comments may also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone 301-415-1966.)

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking web site at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are

problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

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

SUPPLEMENTARY INFORMATION:

- I. Background
 - A. Development of Proposed Rule.
 - B. Publication of Revised Proposed Rule.
- II. Reorganization of Part 52 and Conforming Changes in the NRC's Regulations.
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 - F. Proposed Changes to 10 CFR Part 2.
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 - I. Proposed Changes to 10 CFR Part 20.
 - J. Proposed Changes to 10 CFR Part 21.
 - K. Proposed Change to 10 CFR Part 25.
 - L. Proposed Changes to 10 CFR Part 26.
 - M. Proposed Changes to 10 CFR Part 51.
 - N. Proposed Changes to 10 CFR Part 54.
 - O. Proposed Changes to 10 CFR Part 55.
 - P. Proposed Changes to 10 CFR Part 72.
 - Q. Proposed Changes to 10 CFR Part 73.
 - R. Proposed Change to 10 CFR Part 75.
 - S. Proposed Changes to 10 CFR Part 95.
 - T. Proposed Changes to 10 CFR Part 140.
 - U. Proposed Changes to 10 CFR Part 170.
- IV. Specific Request for Comments
- V. Availability of Documents
- VI. Agreement State Compatibility
- VII. Plain Language
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- IX. Environmental Impact - Categorical Exclusion
- X. Paperwork Reduction Act Statement
- XI. Regulatory Analysis
- XII. Regulatory Flexibility Certification
- XIII. Backfit Analysis

I. Background.

A. Development of Proposed Rule.

On July 3, 2003 (68 FR 40026), the NRC published a proposed rulemaking that would clarify and/or correct miscellaneous parts of the NRC's regulations; update 10 CFR part 52 in its entirety; and incorporate stakeholder comments. The NRC is issuing a revised proposed rule that rewrites part 52, makes changes throughout the Commission's regulations to ensure that all licensing processes in part 52 are addressed, and clarifies the applicability of various requirements to each of the processes in part 52 (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license). This proposed rule withdraws and supersedes the July 3, 2003 proposed rule.

The NRC issued 10 CFR part 52 on April 18, 1989 (54 FR 15372), to reform the NRC's licensing process for future nuclear power plants. The rule added alternative licensing processes in 10 CFR part 52 for early site permits, standard design certifications, and combined licenses. These were additions to the two-step licensing process that already existed in 10 CFR part 50. The processes in 10 CFR part 52 resolved safety and environmental issues early in licensing proceedings and were intended to enhance the safety and reliability of nuclear power plants through standardization. Subsequently, the NRC certified three nuclear power plant designs under part B of 10 CFR part 52—the U.S. Advanced Boiling Water Reactor (ABWR) (62 FR 25800; May 12, 1997), the System 80+ (62 FR 27840; May 21, 1997), and the AP600

(64 FR 72002; December 23, 1999) designs and codified these designs in Appendices A, B, and C of 10 CFR part 52, respectively.

The NRC had planned to update 10 CFR part 52 after using the standard design certification process. The proposed rulemaking action began with the issuance of SECY-98-282, "Part 52 Rulemaking Plan," on December 4, 1998. The Commission issued a staff requirements memorandum on January 14, 1999 (SRM on SECY-98-282), approving the NRC staff's plan for revising 10 CFR part 52. Subsequently, the NRC obtained considerable stakeholder comment on its planned action, conducted three public meetings on the proposed rulemaking, and twice posted draft rule language on the NRC's rulemaking Web site before issuance of the initial proposed rule.

B. Publication of Revised Proposed Rule.

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

agency may more effectively and efficiently implement the licensing and approval processes for future nuclear power plants under part 52.

Accordingly, the Commission has decided to revise the July 2003 proposed rule and publish the revised proposed rule for public comment. As discussed in more detail in Section II, *Reorganization of Part 52 and Conforming Changes in the NRC's regulations*, this revised proposed rule contains a rewrite of part 52, as well as changes throughout the NRC's regulations, to ensure that all licensing and approval processes in part 52 are addressed, and to clarify the applicability of various requirements to each of the processes in part 52 (*i.e.*, early site permit, standard design approval, standard design certification, combined license, and manufacturing license). In light of the substantial rewrite of the July 2003 proposed rule, the expansion of the scope of the rulemaking, and the NRC's decision to publish the revised proposed rule for public comment, the NRC has decided that developing responses to comments received on the July 2003 proposed rule is not an effective use of agency resources. The NRC requests that commenters on the July 2003 proposed rule who believe that their earlier comments are not addressed in this proposed rule (or are not adequately addressed), resubmit their comments. The NRC will provide resolutions for comments received on the revised proposed rule in the statement of considerations for the final rule. The NRC will not be providing a comment resolution for all of the comments received on the original July 2003 proposed rule.

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

Since the NRC first adopted 10 CFR part 52 in 1989, the NRC and its external stakeholders have identified a number of interrelated issues and concerns. One significant concern is that the overall regulatory relationship between part 50 and part 52 is not always

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

The language does not explicitly identify the part 50 requirements that are "technically relevant to the design." Even where a specific regulation in part 50 is identified as a requirement, the language of the referenced regulation itself was not changed to reflect the specific requirements as applied to the part 52 processes. For example, § 52.79(b) provides that the application must contain the "technically relevant information required of applicants for an operating license required by 10 CFR 50.34." Other than the fact that this language shares the problem discussed earlier of what constitutes a "technically relevant" requirement, § 50.34(b) is based upon the two-step licensing process whereby certain important information is submitted at the construction permit stage, and then supplemented with more detailed information at the operating license stage. Thus, it could be asserted that certain information that must be submitted in the construction permit application, *e.g.*, the "principal design criteria

for the facility” required by § 50.34(a)(3)(i), may be regarded as not required to be submitted for a combined license application under the current version of part 52.

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

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

Accordingly, the NRC now proposes to take a more comprehensive approach to addressing these issues by reorganizing part 52, implementing a uniform format and content for each of the subparts in part 52, using consistent wording and organization of sections in each of the subparts, and making conforming changes throughout 10 CFR Chapter 1 to reflect the licensing and approval processes in part 52. The NRC has also attempted to coordinate and reconcile differences in wording among provisions in parts 2, 50, 51, and 52 to provide consistent terminology throughout all of the regulations affecting part 52. Under the NRC’s

proposed reorganization of part 52, the existing appendices O and M on standard design approvals and manufacturing licenses, respectively, would be redesignated as new subparts in part 52. Redesignating these appendices as subparts in part 52 would result in a consistent format and organization of the requirements applicable to each of the licensing and approval processes. In addition, the redesignation would clarify that each of the licensing and approval processes in these appendices are available to potential applicants as an alternative to the processes in part 50 (construction permit and operating license) and the existing subparts A through C of part 52. The Commission does not, by virtue of the proposed redesignation, either favor or disfavor the processes in the current appendices M and O. Rather, the Commission is simply attempting to standardize the format and organization of part 52, and to clarify the full range of alternatives that are available under part 52 for use by potential applicants. Consistent with the broad scope of part 52, the NRC proposes to retitle 10 CFR part 52 as “Licenses, Certifications, and Approvals for Nuclear Power Plants.”

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

Appendix N, which addresses duplicate design licenses, would be removed from part 52 and would be retained in part 50 because the duplicate design license is a part 50 operating license. Appendix Q, which addresses early staff review of site suitability issues, would also be

removed from part 52 but retained in part 50. Appendix Q provides for NRC staff issuance of a staff site report on site suitability issues with respect to a specific site for which a potential applicant seeks the NRC staff's views. The staff site report is issued after receiving and considering the comments of Federal, State, and local agencies and interested persons, as well as the views of the Advisory Committee on Reactor Safeguards (ACRS), but only if site safety issues are raised. The staff site report does not bind the Commission or a presiding officer in any hearing under part 2. This process is separate from the early site permit process in subpart A of part 52. The NRC recognizes that there appears to be some redundancy between the early review of site suitability issues and the early site permit process. Accordingly, the NRC proposes to remove appendix Q from part 52 and retain it only in part 50.

Inasmuch as the NRC may, in the future, adopt other regulatory processes for nuclear power plants, the NRC proposes to reserve several subparts in part 52 to accommodate additional licensing processes that may be adopted by the NRC. The NRC used a standard format and content for revising the regulations in the existing subparts and developing the new subparts that address the current appendices M and O. The standard format and content was modeled on the existing organization and content of subparts A and C.

Perhaps most importantly, the NRC has reviewed the existing regulations in 10 CFR Chapter 1 to determine if the existing regulations must be modified to reflect the licensing and approval processes in part 52. First, the NRC determined whether an existing regulatory provision must, by virtue of a statutory requirement or regulatory necessity, be extended to address a part 52 process, and, if so, how the regulatory provision should apply. Second, in situations where the NRC has some discretion, the NRC determined whether there were policy or regulatory reasons to extend the existing regulations to each of the part 52 processes. Most of the NRC's proposed conforming changes occur in 10 CFR part 50. In making conforming changes involving 10 CFR part 50 provisions, the NRC has adopted the general principle of

keeping the technical requirements in 10 CFR part 50 and maintaining all applicable procedural requirements in part 52. However, due to the complexity of some provisions in 10 CFR part 50 (e.g., § 50.34), this principle could not be universally followed. A description of, and bases for, the proposed conforming changes for each affected part follows.

The NRC has prepared the following table that cross-references the proposed reorganized provisions of part 52 with the current requirements in part 52:

Table 1. Cross-References Between Proposed 10 CFR Part 52 and Existing Requirements

<u>Proposed Rule</u>	<u>Existing Requirements</u>
<i>General Provisions</i>	
52.0	52.1
52.1	52.3
52.2	52.5
52.3	None
52.4	52.9
52.5	None
52.6	None
52.7	None
52.8	None
52.9	None
52.10	None
52.10a	52.8
<i>Subpart A – Early Site Permits</i>	
52.11	52.11
52.13	52.13
52.15	52.15

52.16	None
52.17	52.17
52.18	52.18
None	52.19
52.21	52.21
52.23	52.23
52.24	52.24
52.25	52.25
52.27	52.27
52.28	None
52.29	52.29
52.31	52.31
52.33	52.33
52.35	52.35
None	52.37
52.39	52.39

Subpart B – Standard Design Certifications

52.41	52.41 and 52.45
52.43	52.43
52.45	52.45 and 52.49
52.46	None
52.47	52.47
52.48	52.48
52.51	52.51
52.53	52.53

52.54	52.54
52.55	52.55
52.57	52.57
52.59	52.59
52.61	52.61
52.63	52.63
<i>Subpart C – Combined Licenses</i>	
52.71	52.71
52.73	52.73
52.75	52.75
52.77	52.77
None	52.78
52.79/52.80	52.79
52.81	52.81
None	52.83
52.85	52.85
52.87	52.87
52.80	52.89
52.91	52.91
52.93	52.93
52.97	52.97
52.98	None
52.99	52.99
52.103	52.103
52.104	None

52.105	None
52.107	None
52.109	None
52.110	None

Subpart D – RESERVED

Subpart E – Standard Design Approvals

52.131	App. O, Introduction
52.133	None
52.135(a)	App. O, Paragraph 1
52.135(b)	App. O, Paragraph 2
52.135(c)	None
52.136	App. O, Paragraph 3
52.137	App. O, Paragraph 3
52.139	None
52.141	App. O, Paragraph 4
52.143	App. O, Paragraph 5
52.145(a)	App. O, Paragraph 5
52.145(b)	App. O, Paragraph 6
52.145(c)	App. O, Paragraph 7
52.147	None

Subpart F – Manufacturing Licenses

52.151	App. M, Introduction
52.153(a)	App. M, Paragraph 8
52.153(b)	N/A
52.155	App. M, Paragraphs 2 and 4

52.156	App. M, Paragraph 4
52.157	App. M, Paragraphs 2, 4, 5, 6
52.158	App. M, Paragraph 3
52.159	App. M, Paragraph 1
52.161 [RESERVED]	N/A
52.163	App. M, Paragraph 1
52.165	App. M, Paragraph 1
52.167	App. M, Paragraphs 5,6,8, 10
52.169 [RESERVED]	N/A
52.171	App. M, Paragraphs 11 and 12
52.173	App. M, Paragraph 6
52.175	None
52.177	None
52.179	None
52.181	None
<i>Subpart G – RESERVED</i>	
<i>Subpart H – Enforcement</i>	
52.301	52.111
52.303	52.113

III. Discussion of Substantive Changes.

A. Introduction.

The proposed changes in 10 CFR Chapter I are further discussed by part. Proposed changes to parts 52 and 50 are discussed first followed by proposed changes to other parts in numerical order. Within each part, general topics are discussed first, followed by discussion of proposed changes to individual sections as necessary. In addition to the substantive changes, existing rule language was revised to make conforming administrative changes (e.g., identification of regulations containing information collection requirements in § 52.10), correct typographic errors, adopt consistent terminology (e.g. “makes the finding under § 52.103(g)”), correct grammar, and adopt plain English. These changes are not discussed further.

B. Testing Requirements for Advanced Reactors.

This proposed rule would amend §§ 50.43, 52.47(b) (proposed § 52.47(c)), 52.79, and appendix M to part 52 (proposed § 52.157) to achieve consistency in the requirements for testing advanced reactor designs and plants. This amendment would require applicants for a combined license, operating license, or manufacturing license that do not reference a certified advanced reactor design to also perform the design qualification testing required of applicants for design certification under the current § 52.47(b)(2). If a combined license application references a certified design, the qualification testing required by the current § 52.47(b)(2) will have been performed. The codification of testing requirements in § 52.47(b)(2) was a principal issue during the original development of 10 CFR part 52 (see Section II of 54 FR 15372; April 18, 1989). The requirements in § 52.47(b)(2), which demonstrate the performance of new safety features for nuclear power plants that differ significantly from evolutionary light-water reactors or use simplified, inherent, passive, or other innovative means to accomplish their

safety functions (advanced reactors), were included in 10 CFR part 52 to ensure that these new safety features will perform as predicted in the applicant's safety analysis report, that the effects of systems interactions are acceptable, and to provide sufficient data to validate analytical codes. The design qualification testing requirements may be met with either separate effects or integral system tests; prototype tests; or a combination of tests, analyses, and operating experience. These requirements implement the Commission's policy on proof-of-performance testing for all advanced reactors (see Policy Statement at 51 FR 24643; July 8, 1986) and the Commission's goal of resolving all safety issues before authorizing construction.

During the development of 10 CFR part 52, the focus of the nuclear industry and the NRC was on applications for design certification. That is why the testing requirements to qualify new or innovative safety features was only included in subpart B of part 52. Furthermore, the tests to qualify a new safety feature are different than verification tests, which are required by the current § 52.79(c) and performed in accordance with Section XI, "Test Control," of appendix B to part 50. Verification tests are used to provide assurance that construction and installation of equipment (as-built) in the facility has been accomplished in accordance with the approved design.

This amendment also proposes, in §§ 50.43(e)(2) and 52.79(a), a requirement for licensing a prototype plant, as defined in proposed §§ 50.2 and 52.1, if it is used to meet the qualification testing requirements in proposed § 50.43(e). New § 50.43(e) states that, if a prototype plant is used to comply with the testing requirements, the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to compensate for any uncertainties associated with the performance of the new or innovative safety features in the prototype plant. Although the NRC stated that it favors the use of prototypical demonstration facilities and that prototype testing is likely to be required for certification of advanced non-light-water designs (see Policy Statement at 51 FR 24646; July 8,

1986, and Section II of the final rule (54 FR 15372; April 18, 1989) on 10 CFR part 52), this revised proposed rule would not require the use of a prototype plant for qualification testing. Rather, this proposed rule would provide that if a prototype plant is used to qualify an advanced reactor design, then additional requirements may be required for licensing the prototype plant to compensate for any uncertainties with the unproven safety features. Also, the prototype plant could be used for commercial operation. Finally, it would make no sense for the NRC to require qualification testing only for design certification applications (paper designs) and not require testing for applications to build and operate an actual nuclear power plant. Therefore, the NRC proposes to amend the current §§ 50.43, 52.47(b), 52.79, and appendix M to part 52 to implement its intent in adopting part 52 and its policy on advanced reactors that it is necessary to demonstrate the performance of new or innovative safety features through design qualification testing for all advanced nuclear reactor designs or plants (including reactors manufactured under a manufacturing license).

C. Proposed Changes to 10 CFR Part 52.

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

The NRC believes that 10 CFR part 52 should be modified to clarify the use of the terms, *site characteristics*, *site parameters*, *design characteristics*, and *design parameters*, to present the NRC's requirements governing applications for and issuance of early site permits, design approvals, design certifications, combined licenses, and manufacturing licenses in clear and unambiguous terms. The proposed rule adds or revises these terms where necessary to reflect

this clarification. Corresponding changes are made to §§ 52.17, 52.24, 52.39, 52.47, 52.54, 52.79, 52.93, 52.157, 52.158, 52.167, 52.171, and Section III.E of appendices A, B, and C to part 52.

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

In addition, the NRC has revised § 52.79 to include a requirement that a combined license application referencing a certified design must contain information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit. Section 52.79 already contains a requirement that a combined license application referencing an early site permit contain information sufficient to demonstrate that the design of the facility falls within the *parameters* specified in the early site permit. The NRC interprets *parameters* in this case to mean the site characteristics and design parameters as defined in proposed § 52.1. The NRC proposes similar changes to §§ 52.39 and 52.93. The need for these changes became evident during NRC's review of the pilot early site permit applications. Because the NRC is relying on certain design parameters specified in the

early site permit applications to reach its conclusions on site suitability, these design parameters will be included in any early site permit issued. The NRC believes that these changes, in the aggregate, will provide sufficient clarification on the use of the terms in question.

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

Commission review of a combined license application that references a design certification will involve a comparison to ensure that the actual characteristics of the site chosen by the combined license applicant fall within the site parameters in the design certification. Similarly, if a combined license applicant references both an early site permit and a design certification, the NRC will review the application to ensure that the site characteristics in the early site permit fall within the site parameters in the referenced design certification and that the actual characteristics of the certified design fall within the design parameters in the early site permit. For these reasons, the NRC believes it is important to clarify the use of these terms and their applicability to the part 52 licensing processes.

2. Issuance of Combined and Manufacturing Licenses (§§ 52.97 and 52.163).

Current § 50.50 sets forth the NRC's authority to include conditions and limitations in permits and licenses issued by the NRC under part 50. Similar language delineating the NRC's authority in this regard is also set forth in § 52.24 for early site permits, but is not included in part 52 with respect to either combined licenses or manufacturing licenses. There are two

possible ways of addressing this omission: § 50.50 could be revised to refer to combined licenses and manufacturing licenses, or provisions analogous to § 50.50 could be added to part 52. Inasmuch as the NRC's inclusion of appropriate conditions in combined licenses is not a technical matter per se but rather a matter of regulatory authority, the most appropriate location for this provision appears to be in part 52. Inclusion of these provisions in appropriate portions of part 52 would be consistent with the inclusion of an analogous provision applicable to early site permits in § 52.24. Accordingly, the NRC proposes to add the language in §§ 52.97(d) for combined licenses, and 52.163 for manufacturing licenses, which are analogous to § 50.50.

3. General Provisions.

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

The NRC proposes to redesignate current § 52.1, *Scope*, as § 52.0, *Scope; applicability of 10 CFR Chapter 1 provisions*. In proposed § 52.0, paragraph (a) consists of current § 52.1 on the scope of part 52, and paragraph (b) addresses the applicability of 10 CFR Chapter 1 provisions. Currently § 52.1 states that part 52 governs the issuance of early site permits, standard design certifications, and combined licenses for nuclear power facilities licensed under Section 103 or 104b of the Atomic Energy Act of 1954 (AEA), as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). In proposed § 52.0(a), the NRC proposes to revise this provision to include standard design approvals and manufacturing licenses within the scope of part 52 and to restrict licenses issued under part 52 to those issued under Section 103 of the AEA. After passage of the 1970 amendments to the AEA, all licenses for commercial nuclear power plants with construction permits issued after the date of the

amendments were required to be issued as Section 103 licenses. The NRC interprets the 1970 amendment as requiring combined licenses under section 185 to be issued as section 103 licenses.¹ Accordingly, the NRC proposes to revise the scope of part 52 to limit its applicability to licenses issued under Section 103 of the AEA.

The addition of proposed § 52.0(b) stems from the July 3, 2003 (68 FR 40026) proposed rule. In that proposed rule, the NRC proposed a new § 52.5 listing all of the licensing provisions in 10 CFR part 50 that also apply to all of the licensing processes in 10 CFR part 52. This proposed change was in response to a letter dated November 13, 2001, from the Nuclear Energy Institute (NEI) that stated:

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

The purpose of the amendment proposed in 2003 was to clarify that these 10 CFR part 50 provisions are applicable to the licensing processes that were formerly in 10 CFR part 50 (appendices M, N, O, and Q) and are now in 10 CFR part 52, as well as to the new licensing processes for early site permits, standard design certifications, and combined licenses. Although these provisions in 10 CFR part 50 did not refer to the additional licensing processes in 10 CFR part 52, the new § 52.5 was proposed to make it clear that a holder of or applicant for an approval, certification, permit, or license issued under 10 CFR part 52 must

¹This may be an academic distinction, in light of the Energy Policy Act of 2005, P. L. No. 109-58, which removed the need for antitrust reviews of new utilization facilities.

comply with all requirements in these provisions that are otherwise applicable to applicants or licensees under 10 CFR part 50. In preparing the revised proposed rule, the NRC has taken into account the comments it received on the 2003 proposed rule which indicated that the previous change to add § 52.5 was overly broad and would impose burdensome and seemingly inappropriate new requirements on applicants for design certifications that were not warranted for entities that were neither constructing nor operating a reactor.

The NRC agrees that the amendment proposed in 2003 was not sufficiently detailed to make it clear which of the part 50 provisions applied to each of the part 52 licensing processes. The NRC has concluded that the most effective solution to this problem is to make conforming changes to all of the regulations in 10 CFR Chapter 1 that are applicable to the part 52 licensing processes. Accordingly, the NRC has reviewed all of 10 CFR Chapter 1 to identify requirements that apply to one or more of the licensing processes in 10 CFR part 52 and is proposing conforming changes to those requirements. As a result of this effort, the NRC proposes to add new § 52.0(b) which makes it clear that the regulations in 10 CFR Chapter 1 apply to a holder of, or applicant for an approval, certification, permit, or license issued under part 52 and that any license, approval, certification, or permit, issued under 10 CFR part 52 must comply with these regulations.

b. Section 52.1, *Definitions*.

The NRC proposes to amend § 52.1 by adding the definitions for *decommission*, *license*, *licensee*, *manufacturing license*, *modular design*, *prototype plant*, and *standard design approval*. The definition of *decommission* from 10 CFR part 50 would be added to 10 CFR part 52 because the NRC is proposing that part 52 address decommissioning of nuclear power facilities with combined licenses. The definitions of *license* and *licensee* are consistent with the

definitions of the same terms that the NRC is proposing in 10 CFR parts 2 and 50. Definitions of *manufacturing license* and *standard design approval* would be added so that each of the part 52 license types are defined in this section.

The definition of *modular design* would be added to explain the type of modular reactor design to which the NRC intended to refer to in the second sentence of the current § 52.103(g). This special provision for modular designs would be added to part 52 to facilitate the licensing of nuclear plants, such as the Modular High Temperature Gas-Cooled Reactor (MHTGR) and Power Reactor Innovative Small Module (PRISM) designs, that consisted of 3 or 4 nuclear reactors in a single power block with a shared power conversion system. During the period that the power block is under construction, the NRC could separately authorize operation for each nuclear reactor when each reactor and all of its necessary support systems were completed. The NRC believes that the term *modular design* needs to be defined to aid future use of the current § 52.103(g) by distinguishing the intended definition from other definitions for modular design that may be used within the nuclear industry.

The NRC proposes to add a definition for *prototype plant* to explain the type of nuclear power plant that the NRC intended in the current § 52.47(b), and in the proposed §§ 50.43, 52.47, 52.79, and 52.157. A *prototype plant* is a licensed nuclear reactor test facility that is similar to and representative of either the first-of-a-kind or standard nuclear plant design in all features and size, but may have additional safety features. The purpose of the prototype plant is to perform testing of new or innovative safety features for the first-of-a-kind nuclear plant design, as well as being used as a commercial nuclear power facility.

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

The current section on interpretations in § 52.5 is retained and redesignated as § 52.2 and the current section on deliberate misconduct in § 52.9 is retained and redesignated as § 52.4.

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

The NRC proposes to clarify the regulatory structure of part 52 by proposing to add new §§ 52.3, *Written communications*; 52.5, *Employee protection*; 52.6, *Completeness and accuracy of information*; 52.7, *Specific exemptions*; 52.8, *Combining licenses*; 52.9, *Jurisdictional limits*; and 52.10, *Attacks and destructive acts*. The Commission proposes to add § 52.3, *Written communications*, which is essentially identical with the current § 50.4, to address the requirements for correspondence, reports, applications, and other written communications from applicants, licensees, or holders of a standard design approval to the NRC concerning the regulations in part 52.

The Commission proposes to add § 52.5, to address discrimination against an employee for engaging in certain protected activities concerning the regulations in part 52. Accordingly, the Commission proposes to add § 52.5, which is essentially identical with the current § 50.7, with the exception of the addition of a provision on coordination with the requirements in 10 CFR part 19.

The Commission proposes to add § 52.6, which is identical with the current § 50.9, to require that information provided to the Commission by a licensee, a holder of a standard design approval, and an applicant under part 52, and information required by statute or by the NRC's regulations, orders, or license conditions to be maintained by a licensee, holder of a standard design approval, and applicant under part 52 (including the applicant for a standard design certification under part 52 following Commission adoption of a final design certification rule) be complete and accurate in all material respects.

The Commission proposes to add § 52.7, which is essentially identical with current § 50.12, to address the procedure and criteria for obtaining an exemption from the requirements of part 52. Although part 50 contains a provision (§ 50.12) for obtaining specific exemptions, § 50.12 by its terms applies only to exemptions from part 50. Although it would be possible to revise § 50.12 so that its provisions apply to exemptions from part 52, this is inconsistent with the general regulatory structure of 10 CFR, wherein each part is treated as a separate and independent regulatory unit. The NRC notes that the exemption provisions in § 52.7 are generally applicable to part 52, and do not supercede or otherwise diminish more specific exemption provisions that are in part 52, for example the provisions of a specific design certification rule or § 52.63(b)(1) governing exemptions from one or more elements of a design certification rule. An applicant or licensee referencing a standard design certification rule who wishes to obtain an exemption from one or more elements must meet the criteria in the specific design certification rule or § 52.63(b)(1). If the applicant or licensee is unable to demonstrate compliance with those criteria, then it may request an exemption under the more encompassing authority of § 52.7. However, the exemption request must then demonstrate compliance with the additional criteria in § 52.7.

The NRC proposes to add § 52.8, which is essentially identical with the current § 50.31, to clarify the Commission's authority under Section 161.h of the AEA to combine NRC licenses,

such as a special nuclear materials license under part 70 for the reactor fuel, with a combined license under part 52. Although § 50.31 contains a provision allowing a part 50 license, such as an operating license, to be combined with a part 52 license, such as an early site permit, § 50.31 does not address the Commission's authority to combine a part 52 license with a non-part 50 license.

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

The Commission proposes to add § 52.10 because there is no specific provision in part 52 that applies to part 52 processes the Commission's longstanding determination with respect to the lack of need for design features and other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by United States defense activities. That determination, which was upheld by the U.S. Court of Appeals for the D.C. Circuit, *see Siegal v. Atomic Energy Commission*, 400 F.2d 778 (D.C. Cir 1968), is currently codified for part 50 facilities in § 50.13. Although it would be possible to revise § 50.13 so that its provisions apply to part 52 licenses, early site permits, standard design certifications, and standard design approvals, this is inconsistent with the overall regulatory pattern of 10 CFR, whereby each part is treated as a separate and independent regulatory unit. Moreover, any changes to § 50.13 may erroneously be viewed as changes to the Commission's substantive determination on this matter.

For these reasons, the Commission is proposing to add § 52.10, which is essentially identical with § 50.13. Inclusion of this provision in part 52 would make clear that combined licenses, manufacturing licenses, design certification rulemakings, standard design approvals,

and amendments to these licenses, rulemakings, and approvals under part 52 - as with licenses issued under part 50 - need not provide design features or other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by United States defense activities. In adding § 52.10, the Commission emphasizes that it is not changing in any way, nor is it intending to revisit in this rulemaking, the Commission's determination with respect to the lack of need for design features or other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by United States defense activities. The Commission is simply making it clear that its longstanding determination applies to applications under part 52 just as it applies to applications under part 50.

4. Subpart A, Early Site Permits.

a. Emergency Preparedness Requirements for Early Site Permit Applicants.

The NRC proposes to amend §§ 52.17(b), 52.18, and 52.39 to address changes to emergency preparedness requirements for early site permit applicants. The NRC proposes to amend § 52.17(b)(1), which requires that an early site permit application identify physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans. The NRC proposes to add a sentence to require that, if physical characteristics that could pose a significant impediment to the development of emergency plans are identified, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. The NRC believes this addition is necessary to clarify the NRC's expectations in cases where a physical characteristic exists that could pose a significant impediment to the development of emergency plans. Simply

identifying these physical characteristics alone does not provide the NRC with enough information to determine if these characteristics are likely to pose a significant impediment to the development of emergency plans. Similarly, the Commission proposes to amend § 52.18 to require that the Commission determine whether the information required of the applicant by § 52.17(b)(1) shows that there is no significant impediment to the development of emergency plans *that cannot be mitigated or eliminated by measures proposed by the applicant* [emphasis added].

The NRC proposes to amend §§ 52.17(b)(2)(i), 52.17(b)(2)(ii), and 52.18 to clarify that any emergency plans or major features of emergency plans proposed by early site permit applicants must be in accordance with the applicable standards of 10 CFR 50.47 and the requirements of appendix E to part 50. These changes would clarify the standards applicable to emergency preparedness information supplied with an early site permit application. In addition, the Commission proposes to add new § 52.17(b)(3) to require that any complete and integrated emergency plans submitted for review in an early site permit application must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and would operate in conformity with the license, the provisions of the AEA, and the NRC's regulations. The NRC is proposing these amendments for consistency with the requirements in subpart C of part 52 regarding the review of emergency plans at the early site permit stage. The NRC believes that its review of complete and integrated plans included in an early site permit application should be no different than its review of emergency plans submitted in a combined license application, given that the NRC must make the same findings in both cases, namely, that the plans submitted by the applicant provide reasonable assurance that adequate protective measures can and will be

taken in the event of a radiological emergency. The NRC will not be able to make the required finding without the inclusion of proposed inspections, tests, analyses, and acceptance criteria in an early site permit application that includes complete and integrated emergency plans.

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

The NRC proposes to retitle § 52.13 from “Relationship to subpart F of 10 CFR part 2 and appendix Q of this part,” to “Relationship to other subparts,” to reflect the revised scope of this section, which has been refocused on part 52. The reference to Appendix Q and part 2 are no longer needed, consistent with the Commission’s decision (discussed earlier in section II) to remove Appendix Q from part 52.

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

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

The title of § 52.17 would be revised to read, “Contents of applications; technical information,” Section 52.17(a)(1) would be amended to state that the early site permit application should specify the range of facilities for which the applicant is requesting site approval (e.g., one, two, or three pressurized-water reactors). This new language, which is consistent with the language in paragraph 2 of current appendix Q to part 52, provides a clearer and more complete statement of the applicant’s proposal with respect to the facilities which may be located under the early site permit. This facilitates NRC review, as well as providing adequate notice to potentially-affected members of the public and State and local governmental

entities. The NRC assumes that an applicant for an early site permit may not know what type of nuclear plant will be built at the site. Therefore, the application must specify the postulated design parameters for the range of reactor types, the numbers of reactors, etc., to increase the likelihood that approval of the site will resolve issues with respect to the actual plant or plants that the early site permit or construction permit applicant decides to build. In a letter dated November 13, 2001 (comment 27 on draft proposed rule text), NEI stated, "The proposed change is too limited. To address the required assessment of major SSCs [structures, systems, and components] that bear on radiological consequences and all items 52.17(a)(1)(i-viii), industry recommends a new § 52.17a.2." The NRC disagrees with NEI's proposal to have a separate provision for applicants who have not determined the type of plant that they plan to build at the proposed site. The NRC expects that applicants for an early site permit may not have decided on a particular type of nuclear power plant, therefore, § 52.17(a)(1) was revised to address this situation.

The NRC proposes to amend § 52.17(a)(1) to eliminate all references to § 50.34. The references to § 50.34(a)(12) and (b)(10) would be removed because these provisions require compliance with the earthquake engineering criteria in appendix S to part 50 and are not requirements for the content of an application. The reference to § 50.34(b)(6)(v), which requires plans for coping with emergencies, would also be removed. All requirements related to emergency planning for early site permits are addressed in § 52.17(b). Finally, the reference to the radiological consequence evaluation factors identified in § 50.34(a)(1) would be removed and restated in § 52.17(a)(1). The NRC is proposing to modify the existing requirement for early site permit applications to describe the seismic, meteorological, hydrologic, and geologic characteristics of the proposed site to add that these descriptions must reflect appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity,

and time in which the historical data have been accumulated. This proposed addition is to ensure that future plants built at the site would be in compliance with General Design Criteria 2 from appendix A to part 50 which requires that structures, systems, and components important to safety be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunamis, and seiches without loss of capability to perform their safety functions. The design bases for these structures, systems, and components are required to reflect appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated.

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

Two additional requirements would be added § 52.17(a)(1) that are taken from § 50.34(b), and which the NRC believes are applicable to early site permit applicants. Section 52.17(a)(1)(xii) would require applicants proposing to site nuclear power plants on multi-unit sites to include in its application an evaluation of the potential hazards of construction

activities to the structures, systems, and components important to safety of operating units, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation of the existing units are not exceeded as a result of construction activities. This requirement currently exists for applicants for construction permits, operating licenses, and combined licenses. The NRC believes it should also be applicable to applicants for early site permits so that all applicable issues are included in the NRC's review of site suitability before a decision is made on issuance of an early site permit, including issues that affect units already operating on the site (if this matter is addressed and resolved in an early site permit, this matter would have finality and need not be addressed in a referencing combined license proceeding). Section 52.17(a)(1)(xiii) would require that early site permit applications include an evaluation of the site against the applicable sections of the Standard Review Plan revision in effect 6 months before the docket date of the application. This requirement currently exists for applicants for construction permits, operating licenses, design certifications, design approvals, combined licenses, and manufacturing licenses. The NRC believes it should also be applicable to applicants for early site permits because they are partial construction permits that can be referenced in applications for construction permits or combined licenses.

The NRC would amend § 52.17(a)(2) to clarify that an early site permit applicant has the flexibility of either addressing the matter of alternative energy sources in the environmental report supporting its early site permit application, or deferring consideration of alternative energy sources to the time that the early site permit is referenced in a licensing application. The NRC believes the current regulations already afford the early site permit applicant such flexibility, inasmuch as § 52.17(a)(2) states that the environmental report submitted in support of an early site permit application must "focus on the environmental effects of construction and operation of a reactor, or reactors...." The environmental report's discussion of alternative energy sources

does not, *per se*, address the “environmental effects of construction and operation of a reactor,” which is one of the matters which must be addressed in an environmental impact statement (EIS). [See 10 CFR 51.71(d); National Environmental Policy Act of 1969 (NEPA), Sec. 102(2)(C)(i), (ii), and (v).] Rather, alternative energy sources constitute part of the discussion of reasonable alternatives to the proposed action, which is required by Sec. 102(2)(C)(iii) of NEPA. [See 10 CFR 51.71(e) n.4; 46 FR 39440 (August 3, 1981) (proposed rule that would eliminate consideration of need for power and alternative energy sources at operating license stage), at 39441 (first column) (final rule published March 26, 1982; 47 FR 12940)]. See *Exelon Generation Company, LLC et al.*, CLI-05-17, 62 NRC 5, where the Commission ruled that:

[T]he “reasonable alternatives” issue does not apply with full force to ESP (or “partial” construction permit) cases. At the ESP stage of the construction permit process, the boards’ “reasonable alternatives” responsibilities are limited because the proceeding is focused on an appropriate *site*, not the actual construction of a reactor. Thus, boards must merely weigh and compare alternative sites, not other types of alternatives (such as alternative energy sources).

Id. at 48 (citations omitted). Accordingly, the NRC believes that § 52.17(a)(2) already provides the early site permit applicant the flexibility of choosing to defer consideration of alternative energy sources to the time that the early site permit is referenced in a combined license or a construction permit application. The proposed rule would clarify that the early site permit applicant may either include a discussion of alternative energy sources in its environmental report, or defer consideration of the matter. The NRC proposes a conforming amendment to §§ 52.18 and 52.21 to clarify that the NRC’s EIS need not address the need for power or alternative energy sources (and therefore these matters may not be litigated) if the early site permit applicant chooses not to address these matters in its environmental report. The

environmental report and EIS for an early site permit must address the benefits associated with issuance of the early site permit (e.g., early resolution of siting issues, early resolution of issues on the environmental impacts of construction and operation of a reactor(s) that fall within the site characteristics, and ability of potential nuclear power plant licensees to “bank” sites on which nuclear power plants could be located without obtaining a full construction permit or combined license). The benefits (and impacts) of issuing an early site permit must always be addressed in the environmental report and EIS for an early site permit, regardless of whether the early site permit applicant chooses to defer, under § 52.17(a)(2), consideration of the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site. This is because the “benefits...of the proposed action” for which the discussion may be deferred under §§ 52.17(a)(2), are the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site; the benefits which may be deferred under § 52.17(a)(2) are entirely separate from the benefits of issuing an early site permit. The proposed action of issuing an early site permit is not the same as the “proposed action” of constructing and operating a nuclear power plant for which the discussion of benefits (including need for power) may be deferred under §52.17(a)(2).² With this clarification, the NRC does not believe that further changes to the language of §§ 52.17 and 52.18 are necessary.

The NRC would amend § 52.17(c) to clarify that if the applicant wants to request authorization to perform limited work activities, *i.e.*, a limited work authorization (LWA), at the site after receipt of the early site permit, the application must contain an identification and

²The NRC emphasizes that under § 52.17(a)(2), only the discussion of benefits (including need for power) of constructing and operating a nuclear power reactor (or reactors), and the discussion of alternative energy sources, may be deferred. The environmental report must always address the “environmental impacts of construction and operation of a reactor, or reactors, which have characteristics which fall within the postulated site parameters.”

description of the specific activities that the applicant seeks authorization to perform. This request by the early site permit applicant would be separate from but not in addition to a request to perform LWA activities under 10 CFR 50.10(e)(1). The submittal of this descriptive information would enable the NRC staff to perform its review of the LWA request, consistent with past practice, to determine if the requested activities are acceptable under § 50.10(e)(1). If an applicant for a construction permit or combined license references an early site permit with authorization to perform LWA activities at the site and subsequently decides to request authorization to perform LWA activities beyond those authorized under § 52.24(c), those additional activities would have to be requested separately under § 50.10(e)(1).

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

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

Section 52.24 would be amended to provide that the early site permit must state the site characteristics and design parameters, as well as the "terms and conditions," of the early site permit, rather than the "conditions and limitations" as is currently provided. The change would provide consistency with § 52.39(a)(2), and in particular paragraph (a)(2)(iii) of the current regulations, which also refers to "site parameters" (corrected to "site characteristics" in the proposed rule) and "terms and conditions." Section 52.24(c) would be added to require that the

early site permit state the activities that the permit holder is authorized to perform at the site. This change would be consistent with the revision to § 52.17(c) where the applicant must specify the activities that it is requesting authorization to perform at the site under § 50.10(e)(1).

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

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

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

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

g. Section 52.39, *Finality of early site determinations;* and *Section 52.93, Exemptions and variances.*

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

- (1) Questions regarding whether the site characteristics, design parameters, or terms and conditions specified in the early site permit have been met;
- (2) Questions regarding whether the early site permit should be modified, suspended, or revoked; or
- (3) Significant new emergency preparedness or environmental information not considered on the early site permit.

Questions about the referencing application demonstrating compliance with the early site permit are fundamentally questions of compliance with the early site permit. They do not attack the underlying validity of the permit. For example, if a person questions whether the design characteristics of the nuclear power facility that the referencing applicant proposes to construct on the site falls within the design parameters specified in the early site permit, it is a matter of

compliance with the early site permit. These compliance matters are specific to the proceeding for the referencing application, and the NRC concludes that any question about whether the referencing application complies with the early site permit should be regarded as a question material to the proceeding and admissible as a contention in the referencing application proceeding (assuming that all relevant Commission requirements in 10 CFR part 2 such as standing and admissibility are met).

The NRC also regards new emergency preparedness information submitted in the referencing application which materially changes the Commission's determination on emergency preparedness matters as an issue material to the proceeding and admissible as a contention in the referencing application proceeding. Any significant environmental issue material to the combined license application which was not considered in the early site permit proceeding is also subject to litigation during the proceeding on the referencing application to the extent the issue differs from issues discussed or reflects significant new information. Because new emergency planning or environmental information will be identified only at the time a license application referencing the early site permit is submitted to the NRC, the NRC believes it is appropriate to address these issues in the proceeding on the referencing application.

Other questions regarding whether the permit should be modified, suspended, or revoked will be challenges to the validity of the early site permit. These challenges may be framed in many different ways, e.g., a Commission error committed at the time of issuance (i.e., Commission failure to consider relevant information known and available at the time of issuance); or actual changes to the site have occurred since issuance of the permit that render some aspect of the permit irrelevant or inadequate to protect public health and safety or common defense and security. The Commission's process for challenges to the validity of a license is contained in 10 CFR 2.206. Accordingly, the Commission concludes that challenges

to the validity of an early site permit should be processed in accordance with § 2.206. In the Commission's view, a variance is not fundamentally a challenge to the validity of the early site permit, because it requests dispensation from compliance with some aspect of the permit whose validity remains undisputed. Therefore, the Commission concludes that variances should be treated as proceeding-specific issues of compliance that are potentially valid subjects of a contention in a proceeding for a referencing application.

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

The NRC proposes to clarify what aspects of the early site permit are subject to the change restrictions in § 52.39(a)(1) by substituting the phrase, "terms and conditions" of an early site permit for the current term, "*requirements*." Under the proposed language, the NRC may not change or impose new site characteristics, design parameters, or terms and conditions on the early site permit, including emergency planning requirements, unless the special backfitting criteria in § 52.39(a)(1) are satisfied. No substantive change is intended by this clarification; the proposed language would specify more clearly the broad scope of matters in an

early site permit which the NRC intended to finalize. The phrase, “site characteristics, or terms, or conditions, including emergency planning requirements,” would be used consistently throughout § 52.39 and corresponding provisions in the proposed revision to § 52.79.

Section 52.39(a)(2) would describe how the NRC would treat matters resolved in the early site permit proceeding in subsequent proceedings on applications referencing the early site permit, and is drawn from the current language of § 52.39(a)(2). In addition, under the last sentence of proposed § 52.39(a)(2), the NRC would finalize changes to an early site permit’s emergency plan (or major features of it, as contemplated under § 52.17(b)(2)) that are made after the issuance of the early site permit, but only if (1) the approved early site permit’s emergency plan (or major feature) is based upon an emergency plan in use by a licensee of a nuclear power plant; (2) the changes to the early site permit emergency plan are identical to the changes in the referenced licensee’s plan; and (3) the changes in the referenced licensee emergency plan are in compliance with § 50.54(q). The Commission’s proposal is premised on the view that changes to emergency plans which are properly implemented under § 50.54(q) do not require NRC review and approval before implementation. Therefore, by analogy, similar changes to an early site permit’s emergency preparedness plan made with similar controls should not require NRC review and approval as part of the licensing process. Any issues with compliance with § 50.54(q) should be treated as an enforcement matter.

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

Section 52.39(c) would replace the current criteria in §§ 52.39(a)(2)(i) through (iii), governing how the NRC would treat various issues with respect to the early site permits and its referencing in a combined license application. Matters regarding compliance with the early site permit which would be potentially valid subjects of contention under the proposed rule are listed

in §§ 52.39(c)(1)(i) through (iii), *e.g.*, whether the reactor proposed to be built under the referencing application fits within the site characteristics and design parameters specified in the early site permit; whether one or more of the terms and conditions of the early site permit have been met; and whether a variance requested by the referencing applicant is unwarranted or should be modified. Matters regarding significant new emergency preparedness or environmental information material to the combined license proceeding, which would be potentially valid subjects of contention under the proposed rule, are listed in §§ 52.39(c)(1)(iv) and (v).

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

The proposed rule would redesignate the current provision in § 52.39(b) allowing an applicant for a license referencing an early site permit to request a variance from one of more “elements” of the early site permit as § 52.39(d). The proposed rule would clarify what “elements” a variance may be sought by substituting the phrase, “site characteristic, design parameter, term, or condition.” The Commission notes that the admission of a contention on a proposed variance, which is currently addressed in § 52.39(b), would now be addressed in § 52.39(c)(iii) of the proposed rule. Finally, the proposed rule would preclude the Commission from issuing a variance once a construction permit, operating license, or combined license

referencing the early site permit is issued; any changes that would otherwise require a variance should instead be treated as an amendment to the combined license.

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

5. Subpart B, Standard Design Certifications.

a. Section 52.41, *Scope of subpart.*

This section defines the scope of subpart B of part 52. The requirements on scope and type of nuclear power plants that are eligible for design certification would be moved from the current § 52.45(a) to this section.

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

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

c. Section 52.45, *Filing of applications.*

This section presents the requirements for filing design certification applications. This section would be formatted for consistency with the other subparts in 10 CFR part 52 and would replace the references to specific paragraphs within §§ 50.4 and 50.30 with references to subpart H of part 2. Specific references are no longer needed because the NRC proposes conforming changes to §§ 50.4 and 50.30 that clarify which provisions are applicable to combined license applications. A new § 52.45(c) on design certification review fees, which are currently set forth in § 52.49, is included.

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

A new section would be added containing the appropriate general content requirements from 10 CFR 50.33 as a conforming amendment.

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

This section presents the requirements for contents of a design certification application. Section 52.47 would be reorganized into separate provisions. The requirements for the final safety analysis report (FSAR) are proposed in §§ 52.47(a) and 52.47(c), and the technical requirements for the remainder of the design certification application are proposed in § 52.47(b). The current § 52.47(a)(1)(i) requires the submittal of information required of applicants for construction permits and operating licenses by parts 20, 50 (including the applicable requirements from 10 CFR 50.34), 73, and 100, and which is technically relevant to the design and not site-specific. That requirement would be removed and replaced with the relevant requirements from the regulations that describe what must be included in an FSAR. In addition, the Commission proposes to codify technical positions that were developed after part 52 was adopted by the Commission in 1989, such as the proposed requirement in § 52.47(a)(19) requiring an explanation how relevant operating experience was incorporated into the standard design (see SRM on SECY-90-377, dated February 15, 1991, ML003707892). Also, the technical requirements in the regulations that are relevant would be revised to clearly state their applicability to design certifications. In doing so, the NRC has attempted to capture all relevant requirements regarding contents of the FSAR for a design certification application.

A new § 52.47(b) would be added to cover the required technical contents of a design certification application that are not contained in the FSAR. Proposed § 52.47(b)(1) amends the

requirement for a design-specific probabilistic risk assessment (PRA) to clarify that the PRA must be full scope and account for the operating modes and initiating events. This proposed clarification is intended to indicate that the PRA submitted in a design certification application must be a full-scope PRA that comprises three sequential levels, an evaluation of core damage frequency, an evaluation of accident releases, and an evaluation of radiological consequences. In addition, the PRA must account for internal (e.g., loss-of-coolant accident and loss of offsite power) and external (e.g., flooding, seismic events, and fire) events for all modes of plant operation. The risk assessment should use quantified PRA methods rather than seismic margins or simplified vulnerabilities scoping methods such as FIVE, except for instances when accident initiators or scenarios can be justifiably screened out with a sound PRA basis. This clarification is necessary to provide additional guidance to applicants regarding the scope of the PRA that must be submitted with the design certification application. The proposed rule also would conform the statement of the requirement for acceptable inspections, tests, analyses, and acceptance criteria (ITAAC) (proposed § 52.47(b)(2)) with the AEA and the requirements in the current § 52.97(b). This clarification of the current language, which was a condensed version of the language in §§ 52.79(c) and 52.97(b), is intended to avoid any future misunderstandings.

The current § 52.47(b) (proposed § 52.47(c)) would be reorganized by separating the requirements on scope of design and modular configuration from the testing requirements. This is part of the NRC's goal to set forth the procedural requirements for the licensing processes in part 52 and the reactor safety requirements in part 50. As a result, the testing requirements would be relocated to § 50.43(e), and the requirements on scope of design and modular configuration would remain in the proposed § 52.47(c). Also, see the discussion on testing requirements for advanced nuclear reactors in Section B.1 of this document.

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

Section 52.54 would be amended to be more consistent with the parallel provisions in §§ 50.50 and 50.57 by including requirements that, after conducting a rulemaking proceeding and receiving the report submitted by the ACRS, the Commission determines that there is reasonable assurance that the design conforms with the provisions of the AEA, and the Commission's regulations; that the applicant is technically qualified; and that issuance of the design certification will not be inimical to the common defense and security or to the health and safety of the public. In addition, a new § 52.54(a)(8) would be added to indicate that the NRC will not issue a design certification unless it finds that the design certification applicant has implemented the quality assurance program described in the safety analysis report. This requirement is being added to indicate the NRC's expectation that design certification applicants implement the QA program that is required to be included in their application under § 52.47(a)(21). The NRC is also considering whether a parallel requirement should be added to Part 50 (e.g., in a new § 50.54a), similar to the requirements for QA program implementation contained in proposed §§ 50.54(a) and 50.55(f). A new § 52.54(b) would be added, consistent with § 50.50, which states that a design certification shall specify the site parameters and design characteristics and any additional requirements and restrictions of the rule, as the Commission deems necessary and appropriate.

The Commission is proposing to modify § 52.54 to require that applicants for a design certification agree to withhold access to National Security Information from individuals until the requirements of 10 CFR parts 25 and/or 95 are met. Section 52.54 would be amended to include a new paragraph (c) which requires that every standard design certification rule contain a provision stating that, after the Commission has adopted the final design certification rule, the applicant for that design certification will not permit any individual to have access to, or any

facility to possess, Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The NRC believes that this amendment, along with the proposed changes to parts 25, 95, and 10 CFR 50.37, are necessary to ensure that access to classified information is adequately controlled by all entities applying for NRC certifications.

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

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

Section 52.63(a)(1) would include a new provision that explicitly allows the Commission to change the design certification rules in part 52 to make future changes to reduce unnecessary regulatory burden, incorporate the revised § 50.59 change criteria, or change the certification information if the change provides a reduction in regulatory burden and maintains protection to public health and safety and common defense and security. Maintaining protection generally embodies the same safety principles used by the NRC in applying risk-informed decision-making, e.g., ensuring that adequate protection is provided, applicable regulations are met, sufficient safety margins are maintained, defense-in-depth is maintained, and that any changes in risk are small and consistent with the Commission's Safety Goal Policy Statement (refer to NRC's Regulatory Guide 1.174). Changes to the design certification rules must be accomplished through rulemaking, with opportunity for public comment. Once a design certification rule is changed through rulemaking, under proposed § 52.63(a)(2), the provisions would apply to all future applications referencing the design certification rule as well as all current plants referencing the design certification, unless the change has been rendered "technically irrelevant" through other action taken under §§ 52.63(a)(3) or (b)(1). Thus, standardization is maintained by ensuring that any changes to a design certification rule intended to reduce regulatory burden are imposed upon all nuclear power plants referencing the design certification rule.

Section 52.63(a)(1) would be modified to replace "a modification" with "the change," to clarify that the three criteria for changes apply to modifications, rescissions, or imposition of new requirements. Also, proposed § 52.63 is amended to be consistent with its original intent (refer to 54 FR 15372; April 18, 1989) that the special backfit requirements apply to the certification information in the generic design control documents, not to the provisions in the design certification rules, e.g., Section VI.E of appendix A to part 52. Any proposed changes to these

provisions that set forth how the design certification regulations are to be used are controlled by the normal backfit requirements in 10 CFR 50.109.

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

6. Subpart C, Combined licenses.

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

The Commission proposes to modify current §§ 52.39 and 52.79 to require a license applicant referencing an early site permit to update and correct the emergency preparedness information provided under § 52.17(b). The issue of updating an early site permit was first raised by the Illinois Department of Nuclear Safety, who suggested in a September 28, 1994, letter that emergency plans and/or offsite certifications approved as part of an early site permit review be kept up-to-date throughout the duration of an early site permit and the construction phase of a combined license.

In SECY-95-090, "Emergency Planning Under 10 CFR Part 52" (April 11, 1995), the NRC staff stated that 10 CFR part 52 does not clearly require an applicant referencing an early site permit to submit updated information on changes in emergency preparedness information or in any emergency plans that were approved as part of the early site permit in accordance

with § 52.18. SECY-95-090 indicated (p. 4) that, in view of the lack of industry interest in pursuing an early site permit, resolution of this matter could be deferred until a “lessons learned” rulemaking updating 10 CFR part 52 was conducted after the first design certification rulemakings were issued. Following public release of a draft SECY paper setting forth the NRC staff’s preliminary views on the licensing process for a combined license, NEI submitted a letter dated September 8, 1998 (comment 2.d), which expressed opposition to a requirement for updating emergency preparedness information throughout the duration of an early site permit, absent an application referencing the early site permit. As an alternative to updating throughout the duration of an early site permit, NEI proposed that emergency planning information be updated when an application for a license referencing the early site permit is filed; portions of the emergency plans that are unchanged would continue to have finality under 10 CFR 52.39. In a September 3, 1999, letter, the NRC staff identified updating of emergency preparedness information in early site permits as a possible subject for the part 52 rulemaking.

The Commission agrees in part with the Illinois Department of Nuclear Safety. Emergency plans and/or offsite certificates in support of emergency plans, approved as part of an early site permit review, should be updated. However, emergency plans do not need to be kept up-to-date throughout the duration of an early site permit. There is no need to update the emergency plans approved in an early site permit until the time the permit is referenced in a combined license application. At that time, the emergency plans would have to be reviewed to confirm that they are up-to-date and to provide any new information that may materially affect the Commission’s earlier determination on emergency preparedness, or correct inaccuracies in the emergency preparedness information approved in the early site permit in support of a reasonable assurance determination, in accordance with § 50.47 and appendix E to part 50. In addition, the Commission agrees with NEI that a “continuous” early site permit update requirement would impose burdens upon the early site permit holder without any commensurate

benefit if the early site permit is not subsequently referenced. Accordingly, the Commission has determined that §§ 52.39 and 52.79 should contain an updating requirement to be imposed upon the applicant referencing an early site permit.

A new § 52.39(b) would be added to require an applicant for a construction permit, operating license, or combined license, whose application references an early site permit, to update and correct the emergency preparedness information provided under § 52.17(b). In addition, the applicant must discuss whether the new information could materially change the bases for compliance with the applicable NRC requirements. A parallel requirement is included in proposed § 52.79 to ensure that applicants for combined licenses referencing an early site permit will submit the updated emergency preparedness information. Section 52.39(a)(1)(iii) would also be added stating that the Commission may modify an early site permit if it determines that a modification is necessary based on updated emergency preparedness information provided in a referencing license application. New information that materially changes the bases for compliance includes: (1) Information that substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan; and (2) Information that would constitute a basis for the Commission to modify or impose new terms and conditions on the early site permit related to emergency preparedness in accordance with § 52.39(a)(1). New information that materially changes the Commission's determination of the matters in § 52.17(b), or results in modifications of existing terms and conditions under § 52.39(a)(1) would be subject to litigation during the construction permit, operating license, or combined license proceedings in accordance with § 52.39(c).

Not all new information on emergency preparedness would be subject to challenge in a hearing under § 52.39(c). For example, an emergency plan may have to be updated to reflect current telephone numbers, names of governmental officials whose positions and

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

b. Resolution of ITAAC.

Sections 52.79(c), 52.85, 52.97(a), 52.99, and 52.103(a) and (g) would be amended to provide an applicant for a combined license with a process for resolving certain acceptance criteria in one or more of the inspection, test, analysis, and acceptance criteria (ITAAC) required by the proposed § 52.79(c) before issuance of the combined license. In a letter dated November 13, 2001 (comment 20 on draft proposed rule text), NEI recommended that subpart C be revised to allow for completion of design acceptance criteria (DAC) at the combined license application stage. NEI made this recommendation because applicants might want to complete certain DAC before construction. DAC are special design certification rule ITAAC. DAC set forth processes and criteria for completing certain detailed design information, such as information about the digital instrumentation and control system. DAC were originally

written to be verified as part of the normal, post-combined license, ITAAC verification process; as such, DAC are in essence specialized ITAAC.

The Commission agrees with NEI's recommendation that combined license applicants be permitted to demonstrate DAC completion as part of the combined license application, for several reasons. First, completion of the detailed design matters covered by DAC before the issuance of a combined license is consistent with the Commission's original concept for design certification and issuance of a combined license. When 10 CFR part 52 was adopted, the Commission intended that a design certification contain final and complete design information. Allowing a finding of acceptable completion of DAC before issuance of a combined license is, therefore, consistent with the Commission's original intent. Second, completion of DAC before issuance of the combined license is consistent with the Commission's goal of resolving issues before construction. Determining whether DAC have been successfully completed before issuance of the combined license avoids the possibility that improperly completed DAC will result in the construction of improperly designed structures, systems, and components. Finally, the Commission believes that completion of DAC before issuance of the combined license will enhance public confidence in the overall licensing process because the public will have an opportunity to challenge whether the detailed design has been properly completed before construction begins. Accordingly, the Commission proposes that a finding of successful completion of DAC may be made when a combined license is issued if the combined license applicant demonstrates that the DAC have been successfully completed. This new process would also allow findings on successful completion of inspections or tests of components procured before the issuance of the combined license. These matters would not be revisited after issuance of the combined license.

Section 52.79(c) would be amended to provide a new provision that states that, if the application references an early site permit or a certified design, the application may include a

notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. Sections 52.79(c) and 52.85 would be amended to require that the *Federal Register* notification required by § 52.85 indicate that the application includes this notification, thereby ensuring that the public has adequate notice of the scope and nature of the application which the Commission is being requested to review.

Sections 52.99 and 52.103 would be amended to incorporate rule language from the design certification regulations in 10 CFR part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of appendix A to part 52). During the preparation of the design certification rules for the ABWR and System 80+ designs, the NRC staff and nuclear industry representatives agreed on certain requirements for the performance and completion of the inspections, tests, or analyses in ITAAC. In the design certification rulemakings, the Commission codified these ITAAC requirements into Section IX of the regulations. The purpose of the requirement in proposed § 52.99(b) is to clarify that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been met. Proposed § 52.99(c) would require the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met. For those inspections, tests, or analyses that are completed within 180 days before the scheduled date for initial loading of fuel, § 52.99(c) would require that the licensee notify the NRC within 10 days of the successful completion of ITAAC. This immediate notification is necessary to ensure the NRC has sufficient time to verify successful completion of the ITAAC prior to the licensee's scheduled date for fuel load. Section 52.99(d) would state the options that a licensee will have in the event that it is determined that any of the acceptance

criteria in the ITAAC have not been met. Section 52.99(e) requires the NRC to ensure that the required inspections, tests, and analyses in the ITAAC are performed and also requires the NRC to publish, at appropriate intervals, notice in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses. Finally, § 52.103(h) states that ITAAC do not, by virtue of their inclusion in the combined license, constitute regulatory requirements after the licensee has received authorization to load fuel or for renewal of the license. However, subsequent modifications must comply with the design descriptions in the design control document unless the applicable requirements in the current § 52.97 (proposed § 52.98) and Section VIII of the design certification rules have been complied with.

In a letter dated April 3, 2001 (item 23), NEI requested that the NRC “consider incorporating DCR general provisions into Subpart C as appropriate.” The NRC has decided to add these ITAAC requirements to proposed § 52.99, consistent with NEI's proposal, because it believes that these provisions embody general principles that are applicable to all holders of combined licenses.

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

Section 52.73 would clarify that a design approval issued under proposed subpart E or a site report issued under proposed subpart B of part 52 may also be referenced in an application for a combined license application filed under 10 CFR part 52. This amendment would also add the requirements in the current § 52.63(c) to the new § 52.73(b) to clarify that this requirement applies to applicants for a combined license. This provision requires that, before granting a combined license which references a standard design certification, information normally contained in certain procurement specifications and construction and installation specifications

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

d. Section 52.75, *Filing of applications.*

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

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

Section 52.78 would be deleted, and the requirements applicable to an applicant for, and holder of, a combined license with respect to the training program would be relocated to § 50.120, where the requirements currently exist for holders of operating licenses.

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

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

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

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

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

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

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

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

Accordingly, the Commission proposes to add requirements for descriptions of operational programs. In doing so, the Commission has taken into account NEI's proposal in its letter dated August 31, 2005, to address SRM-SECY-04-0032.

Section 52.79(b) would describe the variant on the requirements in § 52.79(a) for a combined license application that references an early site permit. Section 52.79(a) does not

explicitly require the application to address whether the terms and conditions specified in the early site permit under § 52.24 have been or will be met by the combined license holder, although this is implicit by the inclusion of any terms and conditions in the early site permit. To remove any ambiguity in this matter, § 52.79(b)(3) would require that the FSAR demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the combined license. The NRC's intent, as reflected in the words, "have been met," is that all terms and conditions will be met before issuance of the combined license.

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

Section 52.79(d) would describe the requirements for combined license applications that reference a standard design certification. Section 52.79(d) would state that the FSAR for a combined license application referencing a standard design certification need not contain information or analyses submitted to the Commission in connection with the design certification, but must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design certification. Section 52.79(d) would require that the FSAR demonstrate that the interface requirements established for the design under § 52.47 have been met and that all requirements and restrictions that may have been set forth in the referenced design certification rule be satisfied by the date of issuance of the combined license.

Section 52.79(e) would describe the requirements for a combined license application that references a manufactured reactor. Previously, no guidance was provided regarding a

combined license application that referenced a manufactured reactor. These requirements are similar to those for the content of an FSAR for a combined license referencing a design certification. Specifically, § 52.79(e) states that the FSAR need not contain information or analyses submitted to the Commission in connection with the manufacturing license, but must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site parameters for the manufactured reactor are bounded by the site where the manufactured reactor is to be installed and used. Section 52.79(e) also would require that the FSAR demonstrate that the interface requirements established for the design have been met and that all terms and conditions that have been included in the manufacturing license be satisfied by the date of issuance of the combined license.

Section 52.79 would require that emergency plans submitted with a combined license application be included in the FSAR (proposed § 52.79(a)). This modification is proposed for consistency with current § 50.34 which requires that emergency plans be included in the FSAR for operating license applications.

Section 52.80 would be added to cover the required technical contents of a combined license application that are not contained in the FSAR. These application contents include the PRA, ITAAC, and the environmental report.

The NRC proposes to add a requirement in § 52.80(a) that an applicant submit a plant-specific PRA as part of an application for a combined license. The current § 52.79(b) references § 52.47(a)(1)(v), which requires a design-specific PRA within a design certification application. This amendment would add new § 52.80(a) to require that if an application for a combined license references a standard design certification or standard design approval, or if the application proposes to use a nuclear power reactor manufactured under a manufacturing license under subpart F of this part, the plant-specific PRA must use the PRA for the design certification, design approval, or manufactured reactor, as applicable, and must be updated to

account for site-specific design information and any design changes, departures, or variances. In a letter dated April 3, 2001 (item 11.1a), NEI stated “we agree on the NRC vision for a plant-specific PRA at COL that supplements the DC PRA with any changes that affect the DC PRA plus site-specific (interface) design information.” A requirement would be added to § 52.80(a) that a combined license application that does not reference a certified design must contain a plant-specific PRA.

The purpose of the requirement for a plant-specific PRA is to identify and address potential design and operational vulnerabilities; gain insights about the risk of the design; assess the balance between preventive and mitigative features in the design; determine quantitatively whether the design represents a reduction in risk over current operating plants; and, determine how the risk associated with the new design relates to the Commission’s safety goals.

Section 52.80(a) would require the plant-specific PRA to be full scope and account for the operating modes and initiating events. This proposed clarification is intended to indicate that the PRA submitted in a combined license application must be a full-scope PRA that comprises three sequential levels including an evaluation of core damage frequency, an evaluation of accident releases, and an evaluation of radiological consequences. In addition, the PRA must account for internal (e.g., loss-of-coolant accident and loss of offsite power) and external (e.g., flooding, seismic events, and fire) events for all modes of plant operation. The risk assessment should use quantified PRA methods rather than seismic margins or simplified vulnerabilities scoping methods such as FIVE, except for instances when accident initiators or scenarios can be justifiably screened out with a sound PRA basis. This clarification would provide additional guidance to combined license applicants regarding the scope and level of the PRA that must be submitted with the combined license application.

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

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

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

The current § 52.83, *Applicability of part 50 provisions*, would be removed and would be replaced by a new section addressing the finality of NRC approvals which are referenced in a combined license application. Current § 52.83 provides that, unless otherwise specifically provided for in subpart C to Part 52, all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits for nuclear power reactors also apply to holders of combined licenses. Similarly, § 52.83 provides that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses issued under this subpart, once the Commission has made the findings required under § 52.99. The Commission believes that the current § 52.83 is not necessary because this proposed rulemaking will provide conforming changes throughout 10 CFR part 50 (as well as all other parts in Title 10 Chapter 1) to identify which requirements are applicable to combined license applicants and holders. Current § 52.83 also provides provisions that address the duration of a combined license and these provisions would be moved to proposed § 52.104, *Duration of combined license*.

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

i. Section 52.89, *Environmental review.*

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

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

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

k. Section 52.93, *Exemptions and variances.*

Section 52.93 would include a discussion of the requirements regarding requests for an exemption from any part of a referenced design certification rule. The proposed § 52.93 states that, if the request is for an exemption from any part of a referenced design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced design certification rule, or with § 52.63 if there are no applicable exemption provisions in the referenced design certification rule.

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

The NRC would modify § 52.97 to be more consistent with the parallel provision in § 50.50, *Issuance of licenses and construction permits*, by including requirements that, after conducting a hearing and receiving the report submitted by the ACRS, the NRC finds that there is reasonable assurance that the applicant is technically and financially qualified to engage in activities authorized; and that issuance of the license will not be inimical to the common defense and security or to the health and safety of the public. Section 52.97(c) would be added, consistent with § 50.50, which states that a combined license shall contain conditions and limitations, including technical specifications, as the Commission deems necessary and appropriate. Existing § 52.97(b)(2) would be moved to new § 52.98, because the issues addressed in this section are issues associated with finality of combined license provisions.

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

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

Section 52.98 would include provisions to clarify the applicability of the change processes in 10 CFR part 50 and Section VIII of the design certification rules in 10 CFR part 52 to a combined license. Section 52.98(b) states that the change processes in 10 CFR part 50

apply to a combined license that does not reference a design certification rule or a reactor manufactured under a manufacturing license. Section 52.98(c) states that the change processes in Section VIII of the design certification rules apply to changes within the scope of the referenced certified design. However, if the proposed change affects the design information that is outside of the scope of the design certification rule, the part 50 change processes apply unless the change also affects the design certification information. For that situation, both change processes may apply.

Section 52.98(d) would be added to address changes to a combined license that references a reactor manufactured under a manufacturing license. Section 52.98(d)(1) states that, if the combined license references a reactor manufactured under a subpart F manufacturing license, then changes to or variances from information within the scope of the manufactured reactor's design are subject to the change processes in § 52.171.

Section 52.98(d)(2) states that changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in 10 CFR part 50 (*e.g.*, §§ 50.54, 50.59, and 50.90). The NRC proposes all of these requirements to clarify, in one location, the finality provisions applicable to all portions of a combined license.

Finally, the Commission proposes to add a new paragraph (g) to the "finality" section in each subpart of part 52, including § 52.98, entitled "Information requests," which would delineate the restrictions on the NRC for information requests to the holder of the combined license. This provision is analogous to the current provision on information requests in paragraph 8 of appendix O to parts 50 and 52, and is based upon the language of § 50.54(f). For combined licenses, this proposed provision would be contained in § 52.98(g), and would require the NRC to evaluate each information request of the holder of a combined license to determine that the burden imposed by the information request is justified in light of the potential safety significance of the issue to be addressed in the information request. The only exceptions

would be for information requests seeking to verify compliance with the current licensing basis of the facility. If the request is from the NRC staff, the request would first have to be approved by the Executive Director for Operations (EDO) or his or her designee.

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

Section 52.103(g) currently requires the NRC to find that the acceptance criteria in the combined license are met before operation of the facility, but does not refer to loading of fuel. However, current § 52.103(f) states that fuel loading and operation under the combined license will not be affected by the granting of a petition to modify the terms and conditions of the combined license unless a Commission order is made immediately effective. It was the Commission's intent in the 1989 rulemaking that it find that the acceptance criteria have been met before fuel is loaded, and the failure to include the reference to loading of fuel was an inadvertent oversight. Therefore, this section would be amended to require the NRC to find that the acceptance criteria in the combined license are met before fuel load and operation of the facility. In addition, Section IX in each of appendices A, B, and C of part 52 requires that the Commission find that the acceptance criteria in the ITAAC for the license are met before fuel load. The NRC believes that this is the common interpretation of § 52.103(g).

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

Five new provisions would be added to Part C for consistency with the other subparts in 10 CFR part 52 and to parallel requirements in 10 CFR part 50 for operating licenses. Section

52.104, would address the duration of a combined license and contains requirements that currently exist in § 52.83. In addition, the Commission proposes to amend these requirements to indicate that, where the Commission has allowed operation under a combined license during an interim period under § 52.103(c), the period of operation is not to exceed 40 years from the date allowing operation during the interim period.

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

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

7. Subpart D, Reserved.

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

Appendix O to part 52 currently sets forth the NRC's requirements for approval of standard designs for nuclear plants or a major portion of a nuclear plant. This licensing process was first adopted by the NRC in 1975 and has been used many times, including issuance of four final design approvals (FDAs) under appendix O to part 52 from 1994 through 2004. These FDAs were issued as part of four design certification reviews where the FDAs were a prerequisite to certification of the standard design. As part of this rulemaking, the NRC proposes to remove the requirement that FDAs are a prerequisite to a design certification under subpart B of part 52 (see the discussion on 10 CFR 52.43).

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

The NRC continues to believe that the best approach for obtaining early resolution of design issues is through the design certification process in subpart B of part 52. Design certification will provide greater finality and standardization than the design approval process. Consequently, the NRC favors the use of the design certification process, which suggests that the design approval process could be eliminated. However, given the frequent use of

appendix O to part 52 in the past, the NRC proposes to retain this process and to reorganize and reformat the design approval process to be consistent with the other subparts.

The language that is currently in appendix O of part 52 has been relocated to a new subpart and formatted to be consistent with the other subparts. A new section (§ 52.133) would be created to describe the relationship of the design approval process with the other subparts. The proposed filing requirements are consistent with the other subparts. The applications may still request approval of either the entire facility or major portions thereof, but the applications are limited to final design information.

There are several reasons for this change. First, the Commission's recent experience with FDAs and design certifications demonstrates that nuclear power plant designers are technically capable of developing essentially complete and final design information for Commission review and approval. Furthermore, the economic incentives with respect to design certification also apply to final design approvals. In addition, approval of a final reactor design removes the unpredictability of issuing a construction permit that references only preliminary design information and initiating construction while the final design information is being completed. Approval of a final standard design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the construction of the plant, which will greatly enhance regulatory stability and predictability.

The NRC also proposes that applications for standard design approvals provide essentially the same technical information that is required for design certification applications (e.g., demonstration of compliance with any technically relevant Three Mile Island (TMI) requirement, proposed technical resolutions of unresolved safety issues and medium- and high-priority generic safety issues, and a design-specific probabilistic risk assessment). This proposal is consistent with past practice regarding applications for future designs and would implement the Commission's Policy Statements on Severe Reactor Accidents (50 FR 32138;

August 8, 1985) and Nuclear Power Plant Standardization (52 FR 34884; September 15, 1987). However, this proposal would not require applicants for standard design approvals to submit ITAACs because FDAs may be referenced in applications for construction permits or operating licenses under 10 CFR part 50, and the verification process used for part 50 applications does not use ITAAC. In addition, this proposal wouldn't require applicants to consider severe accident mitigation design alternatives.

A new § 52.139, which specifies the standards that will be used to review applications for standard design approvals and new §§ 52.145 and 52.147, which specify the finality and duration of standard design approvals consistent with other subparts would be added. In a letter dated November 13, 2001, NEI commented that "Industry recommends FDAs be valid for 15 years." The NRC agrees with the industry's recommendation. The Commission has decided that the duration of standard design approvals should correspond to the duration of design certifications, inasmuch as both standard design approvals and design certifications constitute approvals of nuclear power plants designs, and the period of effectiveness of the approval from a technical standpoint is not a function of whether the approval is granted by the NRC staff or the Commission.

9. Subpart F, Manufacturing Licenses.

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

Appendix M of part 52 currently sets forth the NRC's requirements governing manufacturing licenses. Appendix M of part 52, which was first adopted by the NRC in 1973, provides for issuance of a license authorizing the manufacture of a nuclear power reactor to be

incorporated into a nuclear power plant under a construction permit and operated under an operating license at a different location from the place of manufacture. Under the current licensing regime in appendix M of part 52, the NRC does not approve a final reactor design to be manufactured before issuance of the manufacturing license. Rather, analogous to the two-step process, the NRC issues a manufacturing license based upon the review of a preliminary design equivalent to that provided in a construction permit application. Upon approval of the preliminary design and associated information, the NRC issues a manufacturing license authorizing the manufacture - but not the removal from the manufacturing site - of one or more nuclear power reactors. Thereafter, manufacturing can commence, although the NRC must approve the final design of the manufactured reactor by license amendment (see appendix M of part 52, paragraph 7, *NOTE*). Under paragraph 8 of Appendix M of part 52, the manufactured reactor may not be removed from the place of manufacture until approval of the final design under paragraph 7 of appendix M of part 52.

When the NRC adopted part 52 in 1989, the NRC did not re-examine the regulatory scheme for manufacturing licenses to determine if the bases for adopting part 52 and the licensing concepts used in part 52 also would be an impetus for proposing changes to the regulatory scheme for manufacturing licenses. Nor did the NRC undertake such a re-examination as part of the process leading to the 2003 proposed rule. However, in view of the substantial reorganization and rewriting of 10 CFR Chapter 1 generally, the NRC has reconsidered the efficacy of the current manufacturing license process in appendix M of part 52 and proposes substantial changes to enhance regulatory effectiveness and efficiency.

The most important shift in the manufacturing license concept proposed by the NRC is that a final reactor design, equivalent to that required for a standard design certification under part 52 or an operating license under part 50, must be submitted and approved before issuance of a manufacturing license. There are several reasons for this shift. First, the Commission's

experience with standard design certifications demonstrates that nuclear power plant designers are technically capable of developing a complete reactor design for Commission review. Furthermore, the economic incentives and limitations with respect to approval of a standard reactor design certification also apply to the approval of a design of a manufactured reactor. Indeed, one could argue that the holder of a manufacturing license may structure the commercial transaction to reduce the economic risk associated with the application for a manufacturing license for a final reactor design, as compared to the economic risk associated with a standard design certification. Second, approval of a final reactor design removes the current awkward regulatory process of issuing a manufacturing license, and subsequently amending the license when a final design is submitted. Approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the actual manufacture of the reactor, which will greatly enhance regulatory stability and predictability. Finally, Commission approval of standardized manufacturing processes, coupled together with the potential for a stable workforce and the application of manufacturing process feedback, has great opportunities for maintaining and even improving the quality and consistency of manufacture, as compared to the traditional method of constructing reactors onsite by a variety of contractors and subcontractors.

The technical information required to be included in an application for a manufacturing license, as set forth in proposed §§ 52.157 and 51.158, reflects both the expansion of the scope of approval to include the final design of the reactor to be manufactured, as well as lessons learned with respect to early site permits. Section 52.157 would require the standard information to be submitted in support of the design of a reactor (derived from the existing requirements in current part 52, subparts B and C) for a standard design certification and combined license. In addition, the application must address the provisions with respect to the demonstration by test, analysis, experience, or a combination thereof of simplified, inherent,

passive, or other innovative means to accomplish safety functions, or the results of testing of a prototype plant, as set forth in proposed revisions to § 50.40 (as discussed separately with respect to § 50.40, these testing and prototype requirements proposed to be incorporated into § 50.40 were derived from the current requirements in § 52.47(b)). Information which must be submitted as part of an application, but is not typically considered part of a final safety analysis report, is identified in § 52.158. This includes a PRA, proposed ITAAC to be used by the licensee who will construct and operate a nuclear power plant at its site using the manufactured reactor, and an environmental report for the manufactured reactor.

The environmental report must address severe accident mitigation design alternatives (SAMDA), similar to standard design certifications, because the design approval stage is usually the most cost-effective opportunity for incorporating design features for addressing severe accidents. The NRC notes that the environmental report need not address environmental impacts associated with the actual manufacture of the reactor at any manufacturing location, inasmuch as a manufacturing license does not represent NRC approval of any specific location, facility, or appurtenance for manufacturing. Rather, the NRC is approving a reactor design for manufacture and the ITAAC for verifying that it has been acceptably manufactured and integrated into a nuclear power facility so that it can be safely operated in accordance with the approved manufactured reactor design, the NRC's regulations, and the requirements of the AEA.

In light of the Commission's review and approval of a final design, the NRC proposes to provide a greater degree of finality to a manufacturing license. Under § 52.171(a)(1) of the proposed rule, the same degree of issue finality accorded to the "certified design" would apply throughout the term of the manufacturing license. Under this provision, the approved design for the manufacturing license could not be changed or modified unless the NRC determines it is necessary either for adequate protection or for compliance with requirements applicable and in

effect at the time the manufacturing license was issued. A comparable requirement is also included in § 52.171(a)(4) which would restrict changes to the design of the manufactured reactor if it is referenced for use in a construction permit, operating license, or combined license. The NRC proposes not to provide the ability of the manufacturing license holder to make changes to the design, site parameters, design characteristics, or terms and conditions under the provisions of 10 CFR 50.59, which is comparable to the design certification process. The NRC believes that one of the key reasons for licensing manufactured reactors is to enhance standardization, one of the original objectives of the 1989 part 52 rulemaking. Unlike design certification, which is an approval of a “paper design,” the NRC’s proposed concept of a manufacturing license is pre-approval of the procurement, manufacturing, and quality assurance processes that translates the approved reactor design into a manufactured assembly in a controlled environment, with the capability to optimize techniques and procedures based upon feedback. Some of these advantages may be lost if each “manufactured” reactor were treated as a “one-off” custom product.

The NRC proposes that the term of a manufacturing license be for no less than 5 or more than 15 years from the date of issuance. The licensee may not commence manufacturing of a reactor less than 3 years before the expiration date, but may continue the manufacturing of a reactor whose manufacture commenced before the 3 year deadline up to license expiration. If, however, an application for renewal is timely-filed with the NRC, manufacturing of a reactor whose manufacture commenced before the 3-year deadline may continue until the time that the NRC completes action on the renewal application in accordance with the Timely Renewal Doctrine of the Administrative Procedure Act (APA). The NRC selected the 3-year deadline as a reasonable period for completing the manufacture of a nuclear power reactor, based in large part upon public statements by various reactor vendors that they have set goals for constructing complete nuclear power plants onsite within 3 years. It seems reasonable, therefore, that a

manufactured reactor, built in a controlled environment using industrial manufacturing processes, would be able to be manufactured in the same 3-year period as the construction of an entire facility onsite. The NRC does not propose to specify, as a separate matter, an earliest and latest date for completion of manufacture of any individual reactor. Section 185 of the AEA directs that “[t]he construction permit shall state the earliest and latest date for completion of the construction or modification.” Inasmuch as a manufacturing license is not a construction permit nor does it authorize “construction,” there does not appear to be any legal need for the manufacturing license to specify, apart from its term, the earliest and latest date of completion of manufacture.

10. Subpart G, Reserved.

11. Appendices A, B, and C - Design Certifications for ABWR, System 80+, and AP600.

The NRC proposes to amend paragraphs VI.B.4, 5, and 6 of the three design certification rules in appendices A, B, and C to part 52 for the U.S. ABWR, System 80+, and AP600 designs, respectively, by substituting the phrase “but only for that *plant*” for the erroneous phrase “but only for that *proceeding*” (emphasis added). The new phrase correctly characterizes the scope of issue resolution in three situations. Paragraph VI.B.4 describes how issues associated with a design certification rule are resolved when an exemption has been granted for a plant referencing the design certification rule. Paragraph VI.B.5 describes how issues are resolved when a plant referencing the design certification rule obtains a license amendment for a departure from Tier 2 information. Paragraph VI.B.6 describes how issues are resolved when the applicant or licensee departs from the Tier 2 information on the basis of

paragraph VIII.B.5, which waives the requirement to get NRC approval. Thus, once a matter (e.g., an exemption in the case of paragraph VI.B.4) is addressed for a specific plant referencing a design certification rule, the adequacy of that matter *for that plant* would not ordinarily be subject to challenge in any subsequent proceeding or action (such as an enforcement action) listed in the introductory portion of paragraph IV.B, but there would not be any issue resolution on that subject matter for *any other plant*. Unfortunately, the three design certification rules use the phrase “but only for that proceeding,” which may lead to the erroneous conclusion that issue resolution exists only in the proceeding in which the matter was approved and/or adjudicated, and not in all subsequent proceedings for that plant.

In letters dated November 12, 2001, and November 13, 2001, respectively, General Electric Company and Westinghouse Electric Company reiterated earlier recommendations the two companies had made that Sections VI.B.4 and 5 of the design certification rules state that exemptions and license amendments have finality “but only for that plant.” For the reasons previously discussed, the NRC proposes to substitute the phrase “but only for that plant,” to clarify that issue resolution on a matter applies in subsequent proceedings for that plant.

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

In an earlier rulemaking (see 64 FR 53582; October 4, 1999), the NRC revised § 50.59 to incorporate new thresholds for permitting changes to a plant as described in the FSAR without NRC approval. For consistency and clarity, similar changes are being proposed for 10 CFR part 52 applicants or licensees. Because of some differences in how the change control requirements are structured in the design certification rules, certain definitions contained in § 50.59 are not necessary for or applicable to 10 CFR part 52 and are not being included in this proposed rule. One definition that the NRC is including, is from § 50.59 for a “Departure from a method of evaluation,” which is appropriate to include in this rulemaking so that the eighth criterion in Paragraph VIII.B.5.b of the design certification rules will be implemented as intended.

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

The proposed amendment to paragraph X.B.3.b reduces the frequency of reporting during the period of construction and increases the frequency of reporting during the application review period. The Commission believes that these changes in the reporting burden balance each other and provide the information needed by the NRC to fulfill its responsibilities in the

licensing of future nuclear power plants. In order to make the finding under § 52.103(g), the NRC must monitor the design changes made under Section VIII of the design certification rules. Frequent reporting of design changes will be particularly important in times when the number of design changes could be significant, such as during the procurement of components and equipment, detailed design of the plant before and during construction, and during preoperational testing. After the facility begins operation, the frequency of reporting would revert to the requirement in paragraph X.B.3.c, which is consistent with the requirements for operating plants.

D. Proposed Changes to 10 CFR Part 50.

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

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

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

The definition for *prototype plant* would be added to explain the type of nuclear reactor that the NRC intends in the proposed § 50.43(e). A prototype plant is a licensed nuclear reactor test facility that is similar to and representative of the first-of-a-kind nuclear plant in all features and size, but may have additional safety features. The purpose of the prototype plant is to

perform testing of new or innovative design features for the first-of-a-kind nuclear plant design, as well as being used as a commercial nuclear power facility.

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

Section 50.10 addresses the circumstances under which a license for a production or utilization facility is required, and describes activities which do not constitute “construction” for purposes of obtaining a license for a nuclear power plant. Section 50.10(b) currently prohibits a person from beginning construction of a production or utilization facility unless a construction permit has been issued. Inasmuch as activities constituting construction (as defined in § 50.10(b)) are authorized under a combined license, § 50.10(b) would be revised to refer to combined licenses.

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

3. Classification and Description of Licenses.

a. Section 50.23, *Construction permits.*

This section currently provides that a construction permit for the construction of a production or utilization facility must be issued before issuance of a license for the facility, and then only upon “due completion” of the facility. The revised section clarifies that if the NRC issues a combined license for a nuclear power plant under part 52, the construction permit and operating license are issued simultaneously (i.e., are merged into a “combined license” under Part C of part 52). This is consistent with Section 185.b of the AEA, which provides the NRC with explicit statutory authority to combine a construction permit and an operating license for a nuclear power plant into a single combined license. The NRC notes that § 50.23 does not preclude the NRC from combining a construction permit and operating license with respect to production facilities or utilization facilities other than nuclear power plants under Section 161.h of the AEA.

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

Section 50.30 establishes the NRC’s general procedural requirements on filing of applications for licenses (including construction permits) for production and utilization facilities. The NRC proposes to make conforming changes throughout § 50.30 to include necessary references to part 52 processes other than design certification (Part H of part 2 governs the filing of standard design certification applications), viz., early site permits, combined licenses, standard design approvals, and manufacturing licenses. In addition, § 50.30(a) would be

revised to ensure that the submission requirements governing applications (and amendments to these applications) in § 52.3 apply to part 52 processes other than design certification.

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

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

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

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

Section 50.33(g) currently addresses radiological emergency response plans for State and local government entities that must be submitted in applications for operating licenses. The proposed rule would make a conforming change to ensure that applicants for combined licenses

must also submit this information, as well as applicants for early site permits who decide under § 52.17(b)(2)(iii) to seek NRC review and approval of complete emergency plans.

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

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

The NRC is proposing to retitle § 50.34 from *Contents of applications; technical information* to *Contents of construction permit and operating license applications; technical information*. Section 50.34(a) currently provides the requirements for the technical contents of an application for a stationary power reactor construction permit, design certification or combined license, and § 50.34(b) provides the requirements for the technical contents of an application for a stationary power reactor operating license application. However, the current version of 10 CFR part 52 provides requirements for design certification and combined license applications that are not consistent with the current version of § 50.34. For example, the current § 52.47 states that an application for design certification must contain the technical information which is required of applicants for construction permits and operating licenses by part 50 which is technically relevant to the design and not site-specific. This would encompass requirements in both §§ 50.34(a) and (b). Also, current § 52.79 states that applications for combined licenses must contain the technically relevant information required of applicants for an operating license

by 10 CFR 50.34, which are found in § 50.34(b). In addition to the requirements for technical information in §§ 50.34(a) and (b), §§ 50.34(c) through (h) provide requirements for the contents of licensing applications related to security plans, compliance with Three Mile Island (TMI) related requirements, combustible gas control, and conformance with the Standard Review Plan. Finally, the Commission notes that the subject of contents of an application is an administrative matter, rather than a strictly technical matter. Therefore, these administrative requirements for part 52 processes are more properly located in part 52, rather than in § 50.34. To provide maximum clarity in the requirements for the content of each of the different types of licensing applications, the NRC proposes to revise § 50.34 to make it applicable to construction permit and operating license applications only and to provide separate sections for the technical contents of applications for the other types of licenses or regulatory approvals in 10 CFR part 52 (early site permits in § 52.17, design certifications in § 52.47, combined licenses in § 52.79, design approvals in § 52.137, and manufacturing licenses in § 52.157). In its proposed revisions to 10 CFR part 52, the NRC has brought forward the requirements from § 50.34 that are applicable to each of the licensing and approval processes in 10 CFR part 52. One exception to this structure is the provisions in § 50.34(f) related to compliance with TMI related requirements. Due to the length and complexity of the requirements in this paragraph, § 50.34(f) would be amended to indicate that each applicant for a design certification, design approval, or combined license under part 52 of this chapter must demonstrate compliance with any technically relevant portions of the requirements in § 50.34(f)(1) through (3), rather than repeating the requirements in each of the relevant sections in part 52.

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

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

environmental protection, and the common defense and security, to manufacturing licenses. Therefore, new provisions in § 50.34a(d) are proposed to address the applicable requirements for combined license applications that parallel the requirements for an operating license application. New provisions in § 50.34a(e) are proposed to address the applicable requirements for applications for design approvals, design certifications, and manufacturing licenses to include: (1) a description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems; and (2) an estimate of the quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations, and the quantity of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations.

f . Section 50.36, *Technical specifications.*

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

appendix O, section O.3, which states that the submittal for review of a standard design shall include the applicable technical information under §§ 50.34 (a) and (b), as appropriate.

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

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

Section 50.36a(a) currently requires each licensee of a nuclear power reactor to include technical specifications to keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable. The existing language in § 50.36a(a) encompasses combined license holders. However, applicants for design certification are also required to include proposed technical specifications on effluents in their applications by virtue of the provision in current § 52.47(a)(1)(i) which states that an application for design certification must contain the technical information which is required of applicants for construction permits and operating licenses by 10 CFR part 50 which is technically relevant to the design and not site-specific. Section 50.36a(a) would be amended to state that each licensee of a nuclear power reactor and each applicant for a design certification will include technical specifications to keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable.

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

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

Section 50.37 currently requires that a license or construction permit applicant agree in writing that it will not permit any individual to have access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. Current § 50.37 also requires that this agreement be part of the application for a license or construction permit and that the agreement of the applicant shall be deemed part of the license or construction permit, whether so stated therein or not. The existing language in § 50.37 encompasses early site permit, combined license, and manufacturing license applicants under 10 CFR part 52 because these products are all licenses. However, the NRC proposes to modify § 50.37 to encompass applicants for design certification and for standard design approvals under 10 CFR part 52 for consistency with the proposed changes to 10 CFR part 25, *Access Authorization for Licensee Personnel*. Part 25 sets forth the Commission's requirements governing the grant of access authorization to classified information to certain individuals, and the Commission is proposing modifications to part 25 to reflect the licensing and regulatory approval processes in part 52. Accordingly, the Commission proposes to make consistent changes to § 50.37. The proposed § 50.37 would require that an applicant for a license, construction permit, design certification, or design approval under part 52 agree in writing that it will not permit any individual to have access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. Proposed § 50.37 would also require that this agreement be part of the

application and be deemed part of the license, or construction permit, or NRC standard design approval whether so stated therein or not. The NRC proposes to modify § 52.54, *Issuance of standard design certification*, to include a new provision which requires that every standard design certification rule issued contain a provision that states that, after the Commission has adopted the final standard design certification rule, the applicant will not permit any individual to have access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The NRC believes that these proposed changes, along with the proposed changes to parts 25 and 95, are necessary to ensure that access to classified information is adequately controlled by all entities applying for NRC licenses, design certifications, or design approvals.

4. Standards for Licenses, Certifications, and Approvals.

a. Section 50.40, *Common standards.*

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

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

The text and heading of this section would be revised to clarify that certain additional standards and provisions for class 103 licenses apply to applications for combined licenses,

design certifications, and manufacturing licenses issued under part 52, in addition to applications for construction permits and operating licenses issued under part 50.

Section 50.43(e) would be added to clarify that the requirements to demonstrate new safety features by testing, which were previously set forth in part 52, apply to applicants for operating licenses issued under part 50 and applicants for combined licenses, design certifications, and manufacturing licenses issued under part 52. This amendment would conform to the goal of having reactor safety requirements in part 50 and procedural requirements in part 52. Only the requirements in § 50.43(e) apply to applications for design certification. Refer to the generic discussion on testing requirements for advanced reactors in Section III.B of this document.

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

This section would be revised to clarify that the standards for authorizing construction or alteration of a facility also apply to applications for combined licenses issued under part 52.

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

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

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

Section 50.47 and Appendix E to 10 CFR part 50 contain emergency planning requirements for nuclear power plants. These regulations do not clearly address early site permit or combined license applicants or holders. Accordingly, the NRC proposes to make a number of changes in these regulations. Section 50.47(a)(1) currently states that no initial operating license for a nuclear power reactor will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, and that no finding under § 50.47 is necessary for issuance of a renewed nuclear power reactor operating license. Section 50.47(a)(1) would be revised to include combined licenses in these applicability statements. A new § 50.47(a)(1)(ii) would be added to include similar requirements for early site permit applicants that submit complete and integrated emergency plans.

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

Section 50.47(d) currently provides that no NRC or Federal Emergency Management Agency (FEMA) review, findings, or determinations concerning the state of offsite emergency preparedness or the adequacy of and capability to implement State and local or utility offsite emergency plans are required before issuance of an operating license authorizing only fuel loading or low-power testing and training (up to 5 percent of the rated power). Section 50.47(d) further states that a license authorizing fuel loading and/or low-power testing and training may be issued after a finding is made by the NRC that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the

event of a radiological emergency and provides the standards by which the NRC will base such a finding. A new § 50.47(e) would be added to provide essentially parallel provisions for a combined license holder by stating that a combined license holder may not load fuel or operate except as provided in accordance with appendix E to part 50 and, because of the nature of the combined license process, the NRC proposed new § 50.54(gg) that would add a condition to all combined licenses. This is necessary to account for the fact that the combined license will already be issued at the time of the first full or partial participation exercise.

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

Appendix E to part 50 would be revised to conform to the changes proposed for §§ 50.47 and 50.54. The introduction to Appendix E to part 50 states that each applicant for an operating license is required by § 50.34(b) to include in the final safety analysis report plans for coping with emergencies. The NRC proposes to add a parallel statement for combined license applicants, and to add a statement that an early site permit applicant may submit emergency

plans. Similar modifications are proposed in Section III of Appendix E to part 50 regarding the content of final safety analysis reports and early site permit applications. In Section IV of Appendix E to part 50, *Content of Emergency Plans*, the NRC proposes to modify paragraph F.2.a, to address combined licenses in addition to operating licenses.

Paragraph F.2.a currently provides requirements regarding the conduct of full participation exercises and states that a full participation exercise shall be conducted within 2 years before the issuance of the first operating license for full power of the first reactor. Paragraph F.2.a also requires that, if the full participation exercise is conducted more than 1 year before issuance of an operating license for full power, an exercise which tests the licensee's onsite emergency plans shall be conducted within 1 year before issuance of an operating license for full power.

The NRC proposes to designate the requirements for operating licenses as paragraph F.2.a.i, and to add a new paragraph F.2.a.ii that contains the requirements for combined licenses.

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

A new paragraph IV.F.2.a.iii would be added to appendix E to part 50 to require that, if the applicant has an operating reactor at the site, an exercise, either full or partial participation,

be conducted for each subsequent reactor constructed on the site. This exercise may be incorporated in the exercise requirements of paragraphs (2)(b) and (2)(c) of section IV.F. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of this exercise for the new reactor, or if the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) would apply just as they do for the first reactor at a site. This new provision is desirable because of the nature of ITAAC for emergency preparedness requirements. The emergency preparedness ITAAC, specifically ITAAC that will be demonstrated through an exercise, provide the necessary reasonable assurance for programs and facilities associated with the yet-unbuilt reactor. Recent agreements between the NRC and external stakeholders on emergency preparedness ITAAC are based on the understanding that ITAAC on the emergency preparedness exercise would serve to demonstrate various aspects of emergency preparedness (e.g., programs and facilities) that did not warrant their own specific/detailed ITAAC. For example, there is no ITAAC for determining whether an adequate staffing roster exists for the technical support center or emergency offsite facility, but its existence and adequacy could be demonstrated during an exercise. Therefore, appendix E to part 50 requirements for emergency preparedness exercises must be included for the current concepts regarding emergency preparedness ITAAC to be viable. With regard to subsequent reactors, those aspects of an exercise which address currently untested (i.e., unexercised) aspects of emergency preparedness for the proposed new reactor must be addressed in new emergency preparedness ITAAC for the subsequent reactor. If various generic exercise-related aspects of emergency preparedness for the site have been previously addressed and satisfied, then there would be no ITAAC for those emergency preparedness aspects for subsequent reactors.

The NRC also proposes to modify section V of appendix E to part 50, *Implementing Procedures*, which states that no less than 180 days before the scheduled issuance of an operating license for a nuclear power reactor or a license to possess nuclear material, the applicant's detailed implementing procedures for its emergency plan shall be submitted to the Commission. Paragraph V also requires that licensees submit any changes to the emergency plan or procedures to the NRC within 30 days of these changes. The NRC proposes to clarify that paragraph V is also applicable to combined license holders by stating that they must submit their detailed implementing procedures for their emergency plans to the NRC no less than 180 days before the date that the Commission authorizes fuel load and operation under § 52.103.

f. Section 50.48, *Fire protection.*

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

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

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

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

Section 50.54 sets forth various provisions that are deemed to be conditions “in every license issued,” while § 50.55 sets forth the provisions deemed to be conditions of every construction permit. In making the conforming changes to these regulations to reflect part 52, the NRC has decided to maintain this dichotomy. Conditions applicable to part 52 processes which are either licenses or prerequisites to licenses, and do not address activities analogous to construction for which a construction permit license is required under the AEA, are proposed to be addressed in § 50.54. By contrast, conditions applicable to part 52 processes which address construction activities, or activities analogous to construction for which a construction permit license is required under the AEA, are proposed to be covered in § 50.55. Combined licenses represent a special case, inasmuch as they address both construction and operation. The NRC proposes to address combined licenses by placing the conditions applicable to construction in §50.55, which would indicate that these conditions are applicable until the date that the NRC authorizes fuel load and operation under § 52.103. Conditions which are applicable during operation would be set forth in § 50.54, and indicate that these conditions are applicable on the date that the NRC authorizes fuel load and operation under § 52.103.

The introductory paragraph of § 50.54 would be revised to refer to combined licenses, and to exclude manufacturing licenses from its provisions. Section 50.54(a)(1) would be revised to indicate that the quality assurance (QA) requirements applicable to operation, as described in a combined license holder’s SAR, become effective 30 days before the scheduled date for the initial loading of fuel.

The NRC proposes to revise § 50.54(i-1) to indicate its applicability to combined licenses. Specifically, § 50.54(i-1) would require that within three months after the date that the

Commission makes the finding under § 52.103(g) for a combined license, the licensee shall have in effect an operator requalification that must, as a minimum, meet the requirements of § 55.59(c) of this chapter.

The NRC proposes to add § 50.54(gg). These revisions are discussed with related requirements in section III.D.4.f of this *Federal Register* document, “Section 50.47, Emergency plans, Section 50.54(gg), and appendix E to part 50, Emergency planning and preparedness for production and utilization facilities.”

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

Sections 50.55(a) and (b) would be revised to require a combined license and manufacturing license to state the earliest and latest dates for completion of construction or modification, and to provide for forfeiture of the combined license or manufacturing license if construction, manufacture, or modification is not completed by the stated date. In the case of a manufacturing license, the license would be required to state the earliest and latest date of manufacture for each reactor. The NRC believes that Section 185.a of the AEA requires that a construction permit state the earliest and latest date for completion of construction, and applies to a combined license because a combined license includes the authority granted under a construction permit. The NRC believes that the 1992 amendment of Section 185.b of the AEA addressing combined licenses did not supercede and render nugatory the provisions of § 50.54a. The NRC believes that the provisions of Section 185 of the AEA do not apply to a manufacturing license, inasmuch as a manufacturing license is not, *per se*, a construction

permit. Nonetheless, because a manufacturing license authorizes activities which are analogous to those in a construction permit, it makes sense from a regulatory standpoint to treat manufacturing licenses similar to construction permits.

Section 50.55(c) makes the conditions in § 50.54 also apply to construction permits, unless otherwise modified. The NRC proposes to retain this paragraph and add a reference to combined licenses. Manufacturing licenses would not be referenced, because there does not appear to be any regulatory need to apply any of the conditions in § 50.54 to manufacturing licenses.

Section 50.55(e) addresses the obligation of holders of construction permits and their contractors and subcontractors, to report defects constituting a substantial safety hazard. These requirements, which implement Section 206 of the ERA, as amended, are comparable to the requirements for licensees in 10 CFR part 21. As discussed with the NRC's proposed changes to part 21, the NRC proposes to retain the current regulatory structure, whereby persons and entities engaged in activities constituting construction (and their contractors and subcontractors) are subject to § 50.55(e), and persons and licensees who are authorized to operate a nuclear power plant (and their contractors and subcontractors) are subject to part 21. Inasmuch as a combined license under part 52 authorizes both construction and operation, a combined license holder would be subject to the reporting requirements in § 50.55(e) from the date of issuance of the combined license until the Commission makes the finding under § 52.103. Thereafter, the combined license holder would be governed by the reporting requirements in part 21. The manufacture of a nuclear power reactor under a manufacturing license is the functional equivalent of construction (albeit limited to the reactor as opposed to the entire facility in the case of a construction permit or combined license). Accordingly, the NRC's view is that the holder of a manufacturing license should be subject to reporting under § 50.55(e). Standard design approvals under proposed subpart E (current appendix M to

part 52) and design certifications under subpart B of part 52 are not directly associated with construction, and the NRC believes that their reporting should be addressed under part 21. Accordingly, the NRC proposes to revise § 50.55(e)(1) to provide that the reporting requirements in § 50.55(e) apply to a holder for a combined license (until the NRC makes the finding under § 52.103(g)), and a manufacturing license under part 52. As discussed below in section J on part 21, early site permits do not authorize “construction” or its functional equivalent. Therefore, early site permits would be subject to the requirements of part 21 rather than § 50.55(e).

Section 50.55(f) sets forth the NRC’s requirements with respect to compliance with the QA requirements in 10 CFR part 50, appendix B, and implementation of the construction permit holder’s QA program as described in its SAR. Comparable provisions applicable to holders of operating licenses are contained in § 50.54(a); requirements governing the SAR’s description of the QA program are contained in § 50.34. A detailed discussion of all changes related to QA requirements can be found in Section III.D.12.b, “Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.”

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

Section 50.55a currently provides requirements relating to codes and standards for construction permits and operating licenses for boiling or pressurized water-cooled nuclear power facilities. The proposed rule would amend § 50.55a to clarify how the regulations in § 50.55a apply to approvals, certifications, and licenses issued under 10 CFR part 52. Section 50.55a currently applies to combined licenses by virtue of the provision in current § 52.83, *Applicability of part 50 provisions*, which states that all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits and operating licenses also

apply to holders of combined licenses. Also, § 50.55a currently applies to design certifications by virtue of the provision in current § 52.48, *Standards for review of applications*, which states that design certification applications will be reviewed for compliance with the standards set out in 10 CFR part 50 as it applies to applications for construction permits and operating licenses for nuclear power plants, and as those standards are technically relevant to the design proposed for the facility. Although current appendix O to part 52 does not explicitly require applicants for design approvals to comply with the requirements of § 50.55a, the NRC is proposing to require design approval holders to comply with § 50.55a because the NRC believes that the requirements for a design approval should be the same as the requirements for design certification, given that the reviews performed by the NRC staff for the two products are essentially identical. Finally, current appendix M to part 52, section M.1, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses. Therefore, the NRC proposes to modify § 50.55a to state that each combined license for a utilization facility is subject to the conditions in § 50.55a, but is only subject to the conditions in §§ 50.55a(f) and (g) after the NRC makes the finding under § 52.103. The proposed modifications to § 50.55a also state that each manufacturing license, design approval, and design certification application is subject to the conditions in §§ 50.55a(a), (b)(1), (b)(4), (c), (d), (e), (f)(3), and (g)(3), which are the provisions related to nuclear power facility design.

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

This section presents a change process for information contained in the FSAR. Section 50.59(b) would be revised to clarify that this change process is applicable to holders of

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

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

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

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

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

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

This section presents the requirements for a maintenance program at nuclear plants. Section 50.65(a) would be revised to clarify that holders of operating licenses issued under part 50 and combined licenses issued under part 52 must have a maintenance program. Section 50.65(c) would be revised to specify that for new licenses issued after the effective date of this regulation, the maintenance program must be implemented before the initial fuel loading of the reactor.

5. Inspections, Records, Reports, Notifications.

a. Section 50.70, *Inspections.*

Section 50.70(a) currently requires that each licensee and each holder of a construction permit allow inspection, by duly authorized representatives of the Commission, of its records, premises, activities, and of licensed materials in possession or use, related to the license or construction permit as may be necessary to effectuate the purposes of the AEA. The existing language in § 50.70(a) encompasses combined license holders and manufacturing license holders because they are licensees. In addition, the provision in current § 52.83, *Applicability of part 50 provisions*, states that all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits and operating licenses also apply to holders of combined licenses. Also, current section M.1 of appendix M to part 52, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security,

to manufacturing licenses. The proposed rule would amend § 50.70(a) to clarify that these inspection requirements also apply to holders of early site permits under 10 CFR part 52. An early site permit is a partial construction permit and therefore should be subject to the same inspection requirements as a construction permit. In addition, the NRC is proposing to clarify that the inspection requirements also apply to applicants for licenses, construction permits, and early site permits. It is common for applicants to perform activities related to NRC regulations before issuance of the license or permit for which they are applying and it has been the NRC's practice to inspect these activities whenever they are performed. Therefore, the proposed modification to require that the inspection requirements in § 50.70(a) apply to applicants is simply a codification of the NRC's current practices.

Section 50.70(b)(1) currently requires that each licensee and each holder of a construction permit provide rent-free office space for the exclusive use of NRC inspection personnel. The current language in this provision encompasses combined license holders and manufacturing license holders. Section 50.70(b)(2) provides requirements regarding the space to be provided for a site with a single power reactor facility licensed under 10 CFR part 50 and for sites containing multiple power reactor units. The NRC proposes to revise § 50.70(b)(2) to clarify that these requirements also apply to sites for combined license holders under 10 CFR part 52 and to facilities issued manufacturing licenses under 10 CFR part 52.

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

Section 50.71 establishes the NRC's requirements for maintenance and retention of records and reports, and updating of FSARs. Section 50.71(a) currently requires each licensee and each holder of a construction permit to maintain all records and make all reports as may be required by license, or by the NRC's regulations. The current language does not apply to

non-licensees, such as holders of standard design approvals and applicants for standard design certifications, even though it would appear that these requirements should apply. Accordingly, the NRC proposes to modify § 50.71(a) to make its provisions applicable to holders of standard design approvals and all applicants for design certification during the period of NRC consideration of the application for design certification, and those applicants for design certification whose designs are certified via rulemaking in accordance with subpart B of 10 CFR part 52.

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

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

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

c. Section 50.73, Licensee event report system.

Section 50.73 currently requires holders of operating licenses under part 50 for nuclear power plants to submit licensee event reports (LERs) on the occurrence of certain operating events to the NRC. LERs facilitate the NRC's oversight of operating nuclear power plants, by alerting the NRC to the occurrence and underlying causes of events having potential safety implications. The NRC's regulatory interest in these events also extends to nuclear power

plants operating under a combined license under subpart C of part 52, but the current language does not impose the LER requirement on combined license holders. Accordingly, in a conforming change, the NRC proposes to extend the LER reporting requirements to holders of combined licenses under part 52 after the Commission has made the finding under § 52.103(g). The proposed rule does not extend the LER requirement to other part 52 processes for similar reasons, *viz.*, the events to be reported under the existing rule concern events which can only occur upon fuel load and operation, and the remaining part 52 licensing and regulatory approval processes do not authorize fuel load or operation.

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

The requirements in § 50.75 are intended to ensure that entities who construct and ultimately operate a nuclear power plant will have sufficient funds at the end of the operational life of the plant to complete the decommissioning of the plant. In brief, § 50.75 currently requires a nuclear power plant operating license application to: (i) address the predicted costs of decommissioning; (ii) describe the method(s) for adjusting the cost prediction throughout the life of the plant to address the effects of inflation; and (iii) provide financial assurance by one of the alternatives specified in the regulation, and to submit evidence that one or more of these means has been established. The regulation also establishes a requirement to update the cost estimates for decommissioning, and to describe any adjustments to the amount of funds collected annually to reflect any changes in projected decommissioning cost.

The current requirements are directed at the two phase construction permit followed by operating license patterns in part 50, and are not well-suited to address the licensing process associated with a combined license under part 52. For example, requiring the combined license applicant to comply with the current requirement in § 50.75(b)(1) that the operating license

applicant submit a copy of the financial instrument obtained to satisfy the requirements of § 50.75(e), would in essence place a more stringent requirement on the combined license applicant inasmuch as it would be required to fund decommissioning assurance at an earlier date as compared with the operating license applicant. To address these discrepancies, the NRC proposes to revise §§ 50.75(b) and 50.75(e)(1) to address decommissioning funding assurance for combined licenses. Under the proposed rule, the combined license applicant must submit a decommissioning report as required by § 50.33(k), but it need not provide a financial instrument to fund decommissioning or to submit a copy to the NRC. Instead, under proposed § 50.75(b)(1) and (4), the combined license must contain a certification that the financial assurance would be provided no later than 30 days after the NRC publishes notice in the Federal Register under § 52.103(a). Following the issuance of a combined license, the holder must submit, by March 31 of each year until the date that the NRC authorizes fuel load under § 52.103(g), an updated certification of the information required by paragraph (b)(1). No later than 30 days after the Commission publishes notice in the *Federal Register* under § 52.103(a), the holder is required to submit a certification that financial assurance is being provided in the relevant amount together with a copy of the financial instrument obtained to satisfy the requirements of § 50.75(e). Once authorization to load fuel and operate is provided to the license holder under § 52.103, the combined license holder is subject to the reporting and updating requirements as an operating license holder under part 50, including the requirements applicable when the plant is within 5 years of the projected end of operation.

The § 50.75 decommissioning funding requirements could be interpreted as applying to an applicant for, and holder of a manufacturing license under part 52. The NRC did not have such intent when it adopted § 50.75. A manufacturing license by itself does not authorize either fuel load or operation, which are the activities necessitating the expenditure of funds for decommissioning. Therefore, there is no need for a holder of a manufacturing license, who

does not intend to operate the reactor being manufactured to provide funding. Accordingly, a conforming change is proposed for §§ 50.33(k) and 50.75(a) to exclude the applicants for and holders of manufacturing licenses under part 52 from compliance with the requirements of that section.

6. US/IAEA Safeguards Agreement.

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

Since 1980, the United States International Atomic Energy Agency (IAEA) Safeguards Agreement has allowed IAEA inspection and verification activities at U.S. facilities that the IAEA selects from the U.S. Eligible Facilities List. The safeguards agreement is implemented under the Nuclear Non-Proliferation Treaty, which provides assurance that all nuclear materials declared to be in peaceful use are not diverted to potential use in nuclear explosives.

Although 10 CFR part 75 contains most of the NRC requirements intended to implement the installation, inspection, and verification provisions of the Safeguards Agreement with IAEA, § 50.78 currently requires each holder of a construction permit to submit certain information on Form N-71, permit verification by representatives of the IAEA, and take any other action necessary to implement the Safeguards Agreement. Inasmuch as combined licenses authorize construction of a nuclear power plant at a fixed site, the provisions of § 50.78 should also apply to a holder of a combined license under part 52. Accordingly, the NRC proposes to revise § 50.78 to specify that holders of combined licenses must, if requested by the NRC, submit installation information on Form N-71, permit verification of that information by the IAEA, and take other action as may be necessary to implement the Safeguards Agreement, in the manner set forth in § 75.6, and §§ 75.11 through 75.14.

7. Transfers of Licenses—Creditors’ Rights—Surrender of Licenses.

a. Section 50.80, *Transfer of licenses.*

Section 50.80 implements Sections 101 and 184 of the AEA, which require Commission approval for the transfer of a license for a production or utilization facility, including a nuclear power reactor. Section 50.80(a) explicitly refers to transfers of a “license for a production or utilization facility . . .,” which would include construction permits under part 50, as well as all licenses and permits issued under part 52. However, to explicitly recognize the applicability of § 50.80(a) to both permits under parts 50 and 52 and all licenses under part 52, § 50.80(a) would be revised to explicitly refer to permits under parts 50 and 52, and licenses under part 52.

b. Section 50.81, *Creditor regulations.*

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

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

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

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

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

Sections 50.92 and 50.91(a)(4) implement the Commission's authority under Section 189 of the AEA to dispense with the advance publication of a *Federal Register* document requesting a hearing with respect to license amendments, and to make operating license and combined license amendments immediately effective upon issuance, if the NRC finds that the amendment involves no significant hazards consideration. The NRC proposes to amend § 50.92(c) to clarify that, consistent with Section 189 of the AEA, the NRC may make a no significant hazards finding for amendments of combined licenses and manufacturing licenses under part 52. Combined licenses are explicitly mentioned in Section 189.a.(2)(A) of the AEA with respect to immediate effectiveness following a Commission determination of a no significant hazards consideration. In addition, a combined license merges into a single license

the authority otherwise contained in a construction permit and an operating license, and the language of Section 189.a.(1)(A) of the AEA which refers to both amendments of construction permits and operating licenses also applies to amendments of combined licenses.

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

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

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

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

approvals. Accordingly, the Commission proposes to revise § 50.100 by adding a new paragraph (b) explicitly addressing the Commission's authority.

10. Backfitting.

a. Section 50.109, *Backfitting*.

The backfit rule provides certain protection to licensees against changes in the NRC requirements and NRC staff positions on those requirements. The backfitting provisions in § 50.109 currently apply to standard design approvals, construction permits, and operating licenses, see § 50.109(a)(1)(i) - (iv), but do not address combined licenses, or manufacturing licenses. Part 52 contains special backfitting requirements on early site permits, design certification rules, but neither § 50.109 or part 52 currently address backfitting of a combined license, although the NRC recognizes that backfitting restraints for an early site permit and a design certification rule would apply to a combined license referencing either or both. To address these gaps in backfitting, and to clarify the application of special backfitting provisions, the Commission is proposing to revise § 50.109(a)(1) by establishing the date that backfitting protection begins for a manufacturing license, a construction permit for a duplicate design license, and a combined license. Moreover, with respect to a part 50 construction permit, a part 50 operating license, and a part 52 combined license, the proposed rule would reference the specific backfitting restrictions that apply if an early site permit, standard design approval, or standard design certification rule is referenced, or if a nuclear power reactor manufactured under a part 52 manufacturing license is used.

11. Enforcement.

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

This section sets forth the requirements for training and qualifying nuclear power plant personnel. The NRC proposes a conforming amendment to add applicants for and holders of combined licenses as being subject to this provision.

12. Appendices.

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

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

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

Appendix B to part 50 states that every applicant for a construction permit is required to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) of the facility and every applicant for an operating license is required to include, in its FSAR, information pertaining to the managerial and administrative controls to be used to assure safe operation. The NRC proposes to revise appendix B to part 50 to clarify that these requirements also apply to early site permits, design approvals, design certifications, combined licenses, and manufacturing licenses under 10 CFR part 52. Specifically, the introduction to appendix B would state that every applicant for a combined license is required by the provisions of § 52.79 to include in its final safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operation. The introduction would also state that, for applications submitted after the effective date of the final rule, every applicant for an early site permit is required by the provisions of § 52.17 to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site. Finally, the introduction would state that every applicant for a design approval, design certification, or manufacturing license is required by the provisions of §§ 52.137, 52.47, and 52.157, respectively, to include in its final safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility.

The NRC proposes to maintain the current regulatory structure for requirements that implement Appendix B whereby QA for construction activities is governed by § 50.55(f), and QA for operation is governed by § 50.54(a). Because a combined license under part 52 authorizes both construction and operation, a combined license holder should be subject to the QA

requirements in § 50.55(f) from the date of issuance of the combined license until the Commission makes the finding under § 52.103(g) that allows the licensee to load fuel and operate. Thereafter, the combined license holder should be governed by the QA requirements in § 50.54(a). The manufacture of a nuclear power reactor under a manufacturing license is the functional equivalent of construction. Accordingly, the NRC proposes to revise § 50.55(f) to refer to holders of manufacturing licenses under part 52. Early site permits under subpart A precede construction and are considered partial construction permits. Hence the NRC believes that they should be subject to QA under § 50.55(f).

Appendix B to part 50 is currently applicable to combined licenses under the provisions of § 52.83, *Applicability of part 50 provisions*, which states that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses. Appendix B to part 50 currently applies to design certifications by virtue of the provision in current § 52.48, *Standards for review of applications*, which states that design certification applications will be reviewed for compliance with the standards set out in 10 CFR part 50 as they apply to applications for construction permits and operating licenses for nuclear power plants, and as those standards are technically relevant to the design proposed for the facility. Appendix O to part 52, section O.3, requires applicants for design approvals to include the information required by §§ 50.34(a) and (b), as appropriate, and states that the information required by § 50.34(a)(7) (a description of the quality assurance program and a discussion of how the applicable requirements of appendix B to part 50 will be satisfied), shall be limited to the QA program to be applied to the design, procurement and fabrication of the SSCs for which design review has been requested. Appendix B to part 50 currently applies to manufacturing licenses by virtue of the provision in current appendix M to part 52, section M.1, which states that the provisions in part 50 applicable to construction permits apply in context, with respect to

matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses.

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

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

The title of Appendix C to part 50 would be revised. Section 182.a of the AEA requires an applicant for a license for a production or utilization facility to submit information in its application... “as the Commission, regulation, may determine to be necessary to decide such of the technical and financial qualifications of the applicant...as the Commission may deem appropriate for the license.” The NRC has long determined the need for non-utility applicants

for nuclear power plant construction permits and operating licenses to establish their financial qualifications, see 10 CFR 50.33(f), and has set forth the specific information on financial qualifications to be provided by applicants for construction permits in appendix C to part 50. Inasmuch as holders of combined licenses under part 52 are authorized to perform the same construction activities with respect to a nuclear power plant as a holder of a construction permit under part 50, the NRC believes that applicants for combined licenses should be subject to the requirements of appendix C to part 50.

With the exception of manufacturing licenses, none of the other regulatory processes under part 52, e.g., early site permits, standard design certifications, and standard design approvals, authorize any activities constituting “construction” under the AEA and the Commission’s regulations.³ Therefore, the proposed rule does not refer to early site permits, design certifications, or design approvals under part 52. With respect to a reactor manufacturing license, the NRC does not believe that a financial qualifications review is necessary for several reasons. A financial qualifications review at the manufacturing license stage would appear to be redundant to the financial qualifications review that is already necessary at the construction permit and operating license stages, or combined license stage. Sufficient safety and quality assurance reviews, including the use of ITAAC in the case of a combined license, should be sufficient to address any adverse impacts on safety as the result of inadequate financial resources to properly manufacture the reactor. Furthermore, the NRC notes that manufacture of a reactor is, in many respects, no different than fabrication of components and systems by third party vendors, who are not required to obtain an NRC license and demonstrate financial qualifications. There seems to be no regulatory value to mandate a

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

financial qualifications review of manufacturing license applicants, when no such review is conducted by the NRC for fabricators of nuclear power plant systems and components.

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

See discussion in Section III.D.4.f of this *Federal Register* notice.

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

The Commission is proposing changes to Appendix I that conform to the changes being proposed in §§ 50.34a and 50.36a. Specifically, a statement would be added in Section I that states that §§ 52.47, 52.79, 52.137, and 52.157 provide that applications for design certification, combined license, design approval, or manufacturing license, respectively, shall include a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems. In addition, Section II would be revised to state that the guides on design objectives set forth in Appendix I may be used by an applicant for a combined license as guidance in meeting the requirements of § 50.34a(d) or by an applicant for a design approval, a design certification, or a manufacturing license as guidance in meeting the requirements of § 50.34a(e). Finally, Section IV would be revised to state that the guides on limiting conditions for operation for light-water-cooled nuclear power reactors in Appendix I may be used by an applicant for an operating license or a design

certification or combined license, or a licensee who has submitted a certification of permanent cessation of operations under § 50.82(a)(1) or § 52.110 as guidance in developing technical specifications under § 50.36a(a) to keep levels of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable.

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

Section 50.54(o) provides a condition for all operating licenses for water-cooled power reactors that primary reactor containments must meet the containment leakage test requirements set forth in Appendix J to part 50. These test requirements provide for preoperational and periodic verification by test of the leak-tight integrity of the primary reactor containment, and systems and components which penetrate containment of water-cooled power reactors, and establish the acceptance criteria for these tests. The purpose of the tests are to assure that (1) leakage through the primary reactor containment systems and components penetrating primary containment shall not exceed allowable leakage rate values as specified in the technical specifications or associated bases; and (2) periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment. The Commission proposes to amend appendix J to part 50 to clarify that these requirements also apply to combined licenses under 10 CFR part 52, as is currently indicated by § 52.83, *Applicability of part 50 provisions*, which states that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses.

g. APPENDICES M and O to Part 50 [Removed].

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

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

Appendix S to part 50 provides earthquake engineering criteria for nuclear power plants and applies to applicants for a design certification or combined license under part 52 or a construction permit or operating license under part 50. The proposed rule would amend appendix S to part 50 to clarify that the requirements in appendix S to part 50 also apply to applicants for design approvals and manufacturing licenses issued under 10 CFR part 52. Although current appendix O to part 52 does not explicitly require applicants for design approvals to comply with the requirements of appendix S to part 50, the NRC is proposing to require design approval holders to comply with appendix S to part 50 because the NRC believes that the requirements for a design approval should be the same as the requirements for a design certification, given that the reviews performed by the NRC staff for the two products are essentially identical. Finally, current appendix M to part 52, section M.1, states that the

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

E. Proposed Change to 10 CFR Part 1.

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

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

F. Proposed Changes to 10 CFR Part 2.

1. Section 2.1, Scope.

The procedures in 10 CFR part 2 apply to, *inter alia*, proceedings concerning standard design approvals and standard design certifications under part 52. Moreover, subpart H of part 2 applied to rulemakings. Accordingly, the statement of scope for part 2 would be revised by adding a reference to rulemaking and standard design approvals.

2. Section 2.4, Definitions

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

3. Section 2.100, Scope of Part .

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

4. Section 2.101, *Filing of Application.*

This section is revised by adding conforming references to combined licenses, early site permits and standard design approvals. The Commission notes that the former language of § 2.101 already applied to combined licenses, as well as early site permits, inasmuch as they are both licenses. Nonetheless, as discussed in the discussion on § 2.4, the definitions of “license” and “licensee” have been revised to explicitly refer to early site permits.

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

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

6. Section 2.104, *Notice of hearing.*

Section 2.104(a) identifies in general the content for notices of hearing published in the Federal Register. Section 2.104(a) would be revised by adding conforming references to a combined license and early site permit, to indicate that the NRC will provide at least 30 days notice in the *Federal Register* of a hearing.

Currently, § 2.104(b) establishes the minimum content of the notice of (mandatory) hearing for a construction permit, and § 2.104(c) establishes the minimum content of the notice of opportunity for hearing for an operating license under part 50. The NRC believes that there is

some benefit, in terms of public transparency and regulatory efficiency and consistency, in establishing the minimum content for notices of hearing for part 52 licensing processes. Accordingly, current § 2.104(d) would be redesignated as § 2.104(l), and § 2.104(e) would be redesignated as § 2.104(m); new §§ 2.104(d), (e), and (f), would be added to establish the content of notices of hearing for early site permits, combined licenses, and manufacturing licenses, respectively. Each of these paragraphs is modeled on the notice of hearing for construction permit, but modified to reflect the criteria for determining the application, as reflected in §§ 52.24, 52.97, and 52.167, for early site permits, combined licenses, and manufacturing licenses, respectively. The NRC notes that manufacturing licenses do not, *per se*, authorize construction of a nuclear power plant. Therefore, a mandatory hearing for a manufacturing license is not required under Section 189.a.(1)(A) of the AEA. The NRC proposes to provide a mandatory hearing as a matter of discretion, in large part because the NRC has never issued a manufacturing license of the type contemplated in proposed subpart F of part 52. Once the NRC has gained experience in the issuance of manufacturing licenses and their oversight, the NRC may in the future remove the requirement for a mandatory hearing associated with a manufacturing license.

Section 2.104(e) currently requires the NRC to transmit a notice of a hearing on an initial application of a license for a production or utilization facility to an appropriate State official and the chief executive of the municipality or county in which the facility is to be located or an activity is to be conducted. As previously noted, the NRC proposes redesignating the § 2.104(e) notice provisions as § 2.104(m). In addition, § 2.104(m)(1) would be revised to clarify that the notice would be provided for applications for early site permits, combined licenses, but not for manufacturing licenses. Manufacturing licenses are excluded from the notification provisions because the NRC is not licensing any particular location or site where manufacturing may occur (see discussion of the manufacturing license concept in Section II.C.9). Because part 52 also

provides an opportunity for hearing with respect to its finding under § 52.103, the NRC proposes to place the language in § 2.104(e)(2) in § 2.104(m)(3), and to add § 2.104(m)(2) which indicates that notice of opportunity for hearing will be provided to the appropriate State official, and the chief executive of the municipality or county as applicable.

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

Section 2.105 contains the NRC's procedures for notices of proposed actions where a hearing is not required by law and if the Commission has determined that a hearing is in the public interest. Inasmuch as amendments to combined licenses and manufacturing licenses do not require a mandatory hearing, § 2.105(a)(4) would be revised to clarify that the procedures in § 2.105 also apply to applications for amendments of combined licenses and manufacturing licenses.

Under current § 52.103(a), the NRC publishes in the *Federal Register* a notice of intended operation and an opportunity to request a hearing with respect to compliance of the facility with inspections, tests, and acceptance criteria in a part 52 combined license. Accordingly, the NRC proposes to revise § 2.105 by adding § 2.105(a)(12) which addresses the notice required by § 52.103(a). Finally, because the Commission's authorization for a combined license holder to operate under § 52.103 does not constitute "issuance" of a license or amendment under § 2.106, § 2.105(b)(3) is added indicating that the Commission will publish a notice of intended operation that identifies the proposed Agency action as making the finding under § 52.103(g).

8. Section 2.106, *Notice of issuance.*

Section 2.106(a) currently provides that the NRC will publish in the *Federal Register* a notice of issuance of a license or amendment of a license where a notice of proposed action has been previously published, and notice of amendment of a nuclear power plant license. However, this section does not require publication of the document in the *Federal Register* that the Commission has made the finding under § 52.103(g). The NRC proposes to revise § 2.106(a) to require publication of such document in the *Federal Register*.

The NRC also proposes to establish in § 2.106(b)(2), the minimum requirements for the contents of such notice, viz., the manner in which copies of the safety analyses, if any, may be obtained and examined, and a finding that the prescribed inspections, tests, and analyses have been performed and that the acceptance criteria prescribed in the combined license have been met, and that the license complies with the requirements of the AEA and the NRC's regulations. These provisions are the same as the existing requirements with respect to notices of issuance for licenses and license amendments, but adds the requirements with respect to ITAAC mandated by Section 185 of the AEA and part 52. The NRC disagrees with the contention raised by the nuclear industry that Section 185 of the AEA limits the NRC to a finding of compliance with respect to ITAAC in determining whether to authorize fuel load and operation for a combined license under part 52. Nothing in the legislative history suggests that by adopting Section 185 of the AEA, Congress intended to override the NRC's long-standing practice of making these findings in connection with all of its regulatory and licensing approvals.

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

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

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

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

11. Section 2.111, Prohibition of sex discrimination.

This section prohibits sex discrimination against certain persons with respect to, *inter alia*, a license under the AEA. This section would be revised to include standard design approvals under part 52, and petitions for rulemaking, including an application for a design certification under part 52.

12. Section 2.202, Orders.

This section would be revised by redesignating § 2.202(e) as § 2.202(e)(1), and adding §§ 2.202(e)(2) through (5), to indicate the backfitting provisions in part 52 applicable to the various licensing processes under part 52. No provisions were deemed necessary to address

issuance of orders representing backfitting of NRC approvals such as standard design approvals. These approvals, by themselves, do not authorize third party action. Therefore, any agency action to condition their use would not require an NRC order to the holder of a standard design approval.

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

Section 2.390(a) contains the Commission's general rule that NRC records and documents regarding a license, permit or order shall ordinarily be made available to the public, unless one or more provisions in § 2.390 apply. This section would be revised to make clear that § 2.390 also applies to NRC records and documents regarding standard design approvals under part 52

14. Section 2.500, *Scope of subpart.*

This section would be revised by adding a conforming reference to subpart F of part 52 on manufacturing licenses.

15. Section 2.501, *Notice of hearing on application under subpart F of part 52 for a license to manufacture nuclear power reactors.*

This section would be revised by adding a conforming reference to subpart F of part 52 on manufacturing licenses. In addition, paragraph (b) of this section would be revised by removing the detailed requirements governing the content of the notice of hearing published in the Federal Register, and instead referencing proposed § 2.104(f). As previously discussed,

the Commission proposes to consolidate in § 2.104, the requirements governing the content of a notice of hearing with respect to all part 52 processes.

16. Sections 2.502, 2.503 and 2.504 are removed and reserved.

The matters addressed in these sections are addressed with greater specificity in proposed subpart F of part 52, consistent with the Commission's proposed concept for manufacturing licenses and the Commission's proposed prohibition on part 50 license applications referencing the use of reactors manufactured under a manufacturing license issued under subpart F of part 52.

17. Section 2.800, *Scope and Applicability*.

Subpart B of part 52 sets out the requirements applicable to Commission issuance of regulations granting standard design certification for nuclear power facilities. Standard design certifications are approved through a rulemaking proceeding, and, in concept, the applicant for a design certification may be considered as a petitioner for rulemaking. However, subpart H of part 2, which sets forth the Commission's procedures governing rulemaking, including petitions for rulemaking, does not specifically address design certification. Furthermore, based upon the Commission's experience with three final design certification rules and a proposed design certification rule, it is clear that some of the procedural requirements applicable to petitions for rulemaking are not well-suited to the administrative process for determining a design certification application, e.g., the existing prohibition against pre-application consultation with the NRC. These consultations between potential license applicants and the NRC staff are not currently prohibited and indeed are encouraged by the Commission to enhance NRC resource

planning and to facilitate early identification and resolution of technical and regulatory issues. An application for design certification is more like a license application than a traditional petition for rulemaking, and the current prohibition against pre-application consulting appears to be inconsistent with the Commission's strategic objectives of safety, effectiveness and management. The Commission also believes, based upon its experience, that administrative provisions ordinarily applied in the context of licensing (e.g., docketing and acceptance review, denial of application for failure to supply information), should also be available for application as appropriate in its determination of design certification applications.

For these reasons, the Commission proposes to revise § 2.800 to address standard design certifications. Section 2.800 would be revised to delineate which provisions of subpart H are applicable to all petitions for rulemaking, and which provisions are applicable only to initial applications for design certification and applications for amendments to existing design certification rules filed by the original applicant (or successors in interest). The title of § 2.800 would be revised to reflect the additional function of this section. Sections 2.811 through 2.819 would be added to address initial applications for design certification as well as applications for amendments to existing design certifications filed by the original applicant (or successors in interest), and are based upon §§ 2.101, 2.107, and 2.109. Petitions for amendment of existing design certification, which are filed by third parties other than the original application for that design certification (or successor in interest), would be treated as an amending petition for rulemaking under the provisions of §§ 2.801-2810.

18. Section 2.801, *Initiation of rulemaking.*

A conforming change is proposed for § 2.801 to refer to applications for standard design certification rulemaking.

19. Section 2.811, *Filing of standard design certification application; required copies.*

Section 2.811 would be added to clarify the requirements that are related to the filing of applications for standard design certifications, and derived from procedural requirements for license applications located in several different regulations in part 50. Section 2.811(a), which is analogous to § 50.4(a), identifies the NRC addresses where an application for a standard design certification must be filed, and provides the requirements for electronic submission of a design certification application. Section 2.811(b), which is analogous to § 50.30(a)(1) and (3), provides that a standard design certification application must meet the written communications requirements in § 2.813. Section 2.811(c), which is analogous to § 50.30(a)(2), requires the applicant to have the capability to make and supply additional copies of the application upon NRC request. Section 2.811(d), which is analogous to the requirement in § 50.30(a)(4), requires the applicant to make a copy of the updated application for use by any party in a hearing conducted under subpart O of part 2 (a legislative-style hearing). Section 2.811(e), which addresses pre-application consultation with the NRC staff, provides that the potential applicant for a design certification may consult with the NRC on the subject matters listed in § 2.802(a)(1)(i) through (iii), including the procedure and process for filing and processing an application for a design certification. However, § 2.811(e) also allows the prospective standard design certification applicant to consult with the NRC staff on substantive technical and regulatory matters relevant to the design certification; the prohibitions in § 2.802(a)(2) do not apply to these consultations.

20. Section 2.813, *Written communications.*

New § 2.813 contains procedural and “housekeeping” requirements governing written communications with the NRC, and are derived from analogous requirements located in several different regulations in part 50. Section 2.813(a) is analogous to § 50.4(a). Section 2.813(b) is analogous to § 50.4(c), and sets forth the requirement that written copies be submitted in permanent form on unglazed paper. Section 2.813(c) is analogous to § 50.4(d), and expresses the Commission’s preference that the upper right corner of the first page of the applicant’s submission set forth the specific regulation or other basis which instigated the written communication.

21. Section 2.815, *Docketing and acceptance review.*

New § 2.815 is analogous to § 2.101(a)(2), and permits the NRC to conduct a review to determine whether the application is complete (i.e., addresses all matters specifically required by NRC regulation to be addressed in an application) and acceptable for docketing. Section 2.815(a) provides that the NRC may determine, in its discretion, the acceptability for docketing of an application based on the technical adequacy of the application, not just on the completeness of the application.

22. Section 2.817, *Withdrawal of application.*

New § 2.817 is analogous to § 2.107, and addresses the procedures that the NRC will follow if a design certification applicant withdraws its application. Section 2.817 also provides for a notice of action on the withdrawal on the NRC Web site if the notice of application was published on the NRC Web site.

23. Section 2.819, Denial of application for failure to supply information.

New § 2.819 is analogous to § 2.108, and states in paragraph (a) that the NRC may deny an application for a standard design certification if the applicant fails to respond to an NRC request for additional information concerning its application within 30 days of the request. Section 2.819(b) provides that the NRC will publish in the *Federal Register* a document denying the application. Section 2.819(b) also states that the NRC will publish a notice on the NRC's Web site denying the application if the NRC previously published a notice of receipt of the application on the NRC Web site.

G. Proposed Change to 10 CFR Part 10.

1. Section 10.1, *Purpose*; and Section 10.2, *Scope*.

Part 10, which contains the NRC's requirements and procedures for determining eligibility for granting access to Restricted Data and National Security Information, does not reflect the licensing and approval processes in part 52. Accordingly, the NRC proposes to make several changes to ensure that there are defined criteria and procedures governing requests for access to Restricted Data and National Security Information by individuals with respect to a license or approval under part 52.

The NRC proposes to add § 10.1(a)(3) which refers to the eligibility of individuals for employment with NRC licensees and applicants, and holders of standard design approvals under part 52, and revise § 10.2(b) to refer to standard design approvals under part 52 and applicants for consultants (to address the provision of services associated with design approvals, who may not be "employees" *per se*).

H. Proposed Changes to 10 CFR Part 19.

Part 19, entitled *Notices, Instructions and Reports to Workers: Inspection and Investigations*, establishes the NRC's requirements for notices, instructions and reports to persons participating in NRC licensed and other regulated activities. For example, it requires licensees and applicants for licenses to post a copy of, *inter alia*, the regulations in 10 CFR parts 19 and 20, and NRC Form 3. NRC Form 3 provides a statement of rights and responsibilities to employees with respect to NRC requirements. Part 19 also establishes the rights and responsibilities of the NRC and individuals during interviews compelled by subpoena as part of a NRC inspection or investigation under Section 161.c of the AEA. Finally, part 19 prohibits, on the grounds of sex, the exclusion from participation in, or being subjected to discrimination under any program or activity licensed by the NRC. The regulatory authority for part 19 stems from Sections 211 and 401 of the Energy Reorganization Act of 1974, as amended (1974 ERA).

The NRC has identified a number of weaknesses with the existing regulatory language in part 19. Currently, part 19's regulatory requirements and proscriptions apply only to licensees who receive, possess, use or transfer material licensed under the NRC's regulations, including persons licensed to operate a production or utilization facility under 10 CFR part 50, but do not cover holders of 10 CFR part 52 licenses such as combined licenses, early site permits, and manufacturing licenses. Moreover, part 19 applies only to licensees who receive, possess, use or transfer materials licensed under 10 CFR parts 30 through 36, 39, 40, 60, 61, 63, 70 or 72 (including persons licensed to operate a production or utilization facility under part 50). Thus, the current regulations would not appear to address discrimination against an employee during "non-operational" activities such as manufacturing or construction of a nuclear power plant. Because the NRC's regulatory scheme relies upon the proper design, manufacture, siting,

and/or construction of a production or utilization facility; discrimination against an employee at any of these stages could have significant adverse public health and safety or common defense and security implications and effects. One would therefore expect that part 19 would apply to such non-operational activities. Finally, part 19 applies only to a “licensee” and activities authorized by a “license,” see, e.g., §§ 19.1, 19.2, 19.11, 19.20, 19.32, and does not extend to part 52's non-licensing regulatory approvals, i.e., standard design approvals and standard design certifications. Inasmuch as these non-licensing activities regulated under part 52 are not different in kind from the licensing which are currently subject to part 19 requirements, the NRC concludes that they should also be subject to the requirements in part 19.

Accordingly, the NRC proposes to amend various provisions in part 19 to ensure that its provisions extend to applicants for and holders of part 50 construction permits, and combined licenses, early site permits and manufacturing licenses under part 52. In addition, the NRC proposes to extend part 19 to cover applicants for and holders of standard design approvals and standard design certifications. The NRC believes that its regulatory authority under Section 211 and Section 401 of the 1974 ERA are much broader than the current scope of part 19. The anti-discrimination proscriptions in Section 211 of the ERA apply to any “employer,” which the NRC regards as including non-licensee entities otherwise regulated by the NRC, such as applicants for and holders of standard design approvals, and applicants for standard design certifications.⁴ The provisions in Section 401 of the ERA, prohibiting sex

⁴The Commission believes that the use of the term, “includes,” in paragraph (a)(2) of Section 211 of the 1974 ERA was not intended to be an exclusive list of the persons and entities subject to the anti-discrimination provisions in that section. The House Report on H.R. 776, which was adopted by Congress as the Energy Policy Act of 1992, states:

[Title V] also broadens the coverage of existing whistle blower protection provisions to include...*any other employer engaged in any activity* under the Energy Reorganization Act of the Atomic Energy Act of 1954.

H.Rep. No. 102-474, part 8, 102d Congress, 2d Sess., at 78-79 (1992)(*emphasis added*).

discrimination apply to “any program or activity carried on...under any title of this Act.”

Accordingly, the NRC concludes that it has the authority to extend the current scope of part 19 to address the non-licensing regulatory approvals in part 52.

To implement the NRC’s proposed broadening of the scope of part 19, §§ 19.1 and 19.2 would be revised to explicitly refer to: (1) applicants for and holders of licenses and permits under part 52; (2) applicants for and holders of final design approvals; and (3) applicants for standard design certifications. The NRC notes that the existing provision in § 19.2 excluding part 19 from applying to NRC employees and contractors remains unchanged in the proposed rule. To provide a convenient term for referring to persons and entities applying for, or granting non-licensed regulatory approvals in part 52, as well as any future regulatory processes, the NRC proposes to amend § 19.3 to the terms, *regulated activities*, and *regulated entities*. Regulated entities would be defined to include (but not be limited to) applicants for and holders of standard design approvals under subpart E of part 52, and applicants for standard design certifications under subpart B of part 52.

Section 19.11 establishes requirements for posting of notices to workers. Because §§ 19.11(a)(2) and (a)(4) contain posting requirements which are not relevant to early site permits, manufacturing licenses, standard design approvals, and standard design certifications, the NRC proposes to delineate in § 19.11(b) the applicable posting requirements for those regulatory processes. Section 19.11(c) is reserved for future Commission use.

Sections 19.14 and 19.20 would be revised to apply to regulated entities, as well as licensees.

Section 19.31, governing exemptions from part 19, would be revised to use language consistent with § 50.12 and proposed § 52.6. Unlike the current regulation, which limits a

There was no discussion of the statutory language in the conference report. H.R. Conf. Rep. No.102-1018, 102d Cong., 2d Sess. (1992).

request for exemption to a “licensee,” the proposed rule would allow “interested persons,” as well as licensees to request an exemption from one or more provisions of part 19. This would allow applicants for and holders of non-license regulatory vehicles in part 52 (standard design approvals and design certifications) to request exemptions from part 19. The broadened scope of persons that would be allowed to request an exemption is consistent with most of the exemption provisions throughout the NRC’s regulations in Title 10 of the CFR, including the specific exemption provision in part 50 (*i.e.*, § 50.12).

Section 19.32 would be revised to more closely track the broad scope of statutory language in Section 401 of the 1974 ERA, which is not limited to licensing, but extends the sex discrimination prohibition to “any ... activity carried on ... under any title” of the ERA. By using the statutory language in the proposed rule, the NRC believes that the regulations would cover not only the existing non-license regulatory vehicles in part 52, but any other regulatory approaches that the NRC may adopt in the future (Section 401 of the 1974 ERA applies to NRC regulatory activities under the AEA, inasmuch as the 1974 ERA transferred the AEA regulatory authority from the old AEC to the NRC, see 1974 ERA, Sec. 104(c)).

I. Proposed Changes to 10 CFR Part 20.

1. Section 20.1002, Scope.

10 CFR part 20 applies to persons licensed by the NRC to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility. Accordingly, § 20.1002 would be revised by adding a conforming reference to part 52, which sets forth a process for licensing a utilization facility.

2. Section 20.1401, *General provisions and scope.*

This section on decommissioning of facilities would be revised to add a conforming reference to facilities licensed under 10 CFR part 52.

3. Section 20.2203, *Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.*

Sections 20.2203(c) and (d) would be revised to add a reference to holders of combined licenses to the procedures on submitting reports.

J. Proposed Changes to 10 CFR Part 21.

Part 21 implements the reporting requirements in Section 206 of the ERA. The proposed part 52 rule published in 2003 set forth the NRC's proposals as to how Section 206 reporting and, therefore, part 21 applicability should be extended to early site permits, standard design certifications, and combined licenses. However, the proposed rule did not address Section 206 reporting requirements with respect to standard design approvals or manufacturing licenses. Moreover, the NRC's proposals were developed without the benefit of the NRC's in-depth consideration of the issues as applied in the context of the early site permit applications that are currently before the NRC. Accordingly, the NRC withdraws its earlier proposal and has developed a more complete and integrated proposal on Section 206 reporting under part 21 and § 50.55(e) (as discussed previously, § 50.55(e) sets forth the Section 206 reporting requirements applicable to holders of construction permits).

Key principles of reporting under section 206 of the ERA.

The NRC believes that the extension of NRC's reporting requirements implementing Section 206 of the ERA to part 52 licensing and approval processes should be consistent with three key principles: First, NRC regulatory requirements implementing Section 206 of the ERA should be a legal obligation throughout the entire "regulatory life" of a NRC license, a standard design approval, or standard design certification. Second, reporting of defects or failures to comply with associated substantial safety hazards should occur whenever the information on potential defects would be most effective in ensuring the integrity and adequacy of the NRC's regulatory activities under part 52 and the activities of entities⁵ subject to the part 52 regulatory regime. Third, each entity conducting activities within the scope of part 52 should develop and implement procedures and practices to ensure that it fulfills its Section 206 of the ERA reporting obligation in an accurate and timely manner.

First principle - Section 206 of the ERA applies throughout "regulatory life."

The first principle, that NRC regulatory requirements implementing Section 206 must extend throughout the entire "regulatory life" of a part 52 process, reflects the regulatory pattern inherent in part 52, whereby certain designated licenses or approvals - e.g., an early site permit, nuclear power reactor manufactured under a manufacturing license, or a design certification - are capable of being referenced in a subsequent nuclear power plant licensing application. Under the part 52 regulatory scheme, a referenced NRC approval constitutes the NRC's basis for the licensing action within the scope of the prior Commission approval, and becomes part of

⁵Throughout this discussion, reference to entities, licensees and/or applicants includes the contractors and subcontractors of those entities, licensees and/or applicants.

the “licensing basis” for that plant. However, if Section 206 of the ERA reflects that effective NRC decision-making and regulatory oversight require accurate and timely information about defects and failures to comply associated with substantial safety hazards, then Section 206 of the ERA should apply whenever necessary to support effective NRC decision-making and regulatory oversight of the referencing licenses and regulatory approvals. To put it in different terms, if the NRC decision that it may safely issue a license depends in part upon an earlier NRC safety determination for a referenced license, standard design approval or standard design certification, it follows that a safety issue with respect to the referenced license, design approval or design certification has safety implications for the referencing license or design certification, and the continuing validity of the NRC’s licensing decision. Thus, the NRC concludes that the need for Section 206 reporting should not be limited to those licenses and approvals under part 52 which are referenced or “relied upon” in a subsequent nuclear power plant licensing application (*viz.*, early site permits, standard design approvals, standard design certifications, and manufacturing licenses), but rather should extend to licenses and approvals that are capable of being referenced in a future licensing application. In other words, they must extend until there can be no further potential safety implications for a referencing license or approval.

The NRC believes that the beginning of the “regulatory life” of a referenced license, standard design approval or standard design certification under part 52 occurs when an application for a license, design approval or design certification is docketed. Docketing of an application marks the start of the NRC’s formal safety and environmental review of the application, and therefore the initiation of the NRC’s need for accurate and timely information to support its regulatory review and approval. However, the NRC cautions that this does not mean that an applicant is without Section 206 responsibilities for pre-application activities. As the NRC staff discussed in a June 21, 2004, letter to NEI (ML040430041) in the context of an early site permit, there are two aspects, namely, a “backward looking” or retrospective aspect with

respect to existing information, and a “forward looking” or prospective aspect with respect to future information. The retrospective obligation is that the early site permit holder and its contractors, upon issuance of the early site permit, must report all known defects or failures to comply in “basic components,” as defined in part 21. The prospective obligation is that the early site permit holder and its contractors must report all defects or failures to comply in basic components discovered subsequent to early site permit issuance. The early site permit holder and its contractors are required to meet these requirements upon issuance of the early site permit, and must continue to meet them throughout the term of the early site permit. Accordingly, safety-related design and analysis or consulting services should be procured and controlled, or dedicated, in a manner sufficient to allow the early site permit holder and its contractors, as applicable, to comply with the above described reporting requirements of Section 206, as implemented by 10 CFR 50.55(e) and part 21.

The NRC believes that the end of regulatory life occurs at the later of: (1) the termination or expiration of the referenced license, standard design approval, or standard design certification; or (2) the termination or expiration of the last of the license or design certification *directly or indirectly referencing* the (referenced) license, design approval, or design certification. For example, if the NRC approves a standard design approval, which is subsequently referenced in a final standard design certification rule, and that standard design certification is, in turn referenced in a combined license issued by the NRC, the “end” of the regulatory life occurs when the authorization to operate under the combined license is terminated (ordinarily, under the provisions of § 52.110). As long as a referenced combined license continues to be effective, the “regulatory life” of a referenced license, standard design approval, standard design certification, or a manufactured reactor (as applicable) must also continue and cannot be deemed to have ended.

Some industry stakeholders have argued that the NRC's regulatory interests would be met if reporting under Section 206 of the ERA were limited to the referencing applicant/licensee, and that there should be no ongoing part 21 reporting obligation imposed on the early site permit holder, original applicant for a standard design certification, or holder of a part 52 regulatory approval. Under this proposal the referencing applicant and licensee would satisfy its obligation by an appropriate contractual provision between the referencing applicant/licensee and the entity "supplying" the referenced license or regulatory approval. Although this could be a viable alternative for some combined licenses, early site permits and standard design approvals, the approach would not be effective in at least three different contexts. This approach would not result in reporting of defects to the NRC by the applicant of the early site permit or standard design certification, which violates the NRC's second principle (discussed more fully in the next section). In addition, this approach would not result in reporting where there is no contractual relationship between the combined license applicant/licensee and the original applicant of the standard design certification. Because the approach suggested by these stakeholders does not satisfy the NRC's regulatory objectives, it is not adopted.

One of the original applicants for the current standard design certifications stated that any arguable Section 206 requirements must logically end upon expiration of the standard design certification, inasmuch as expiration marks the end time that the standard design certification may be referenced. The NRC disagrees with this position. Under § 52.55(b) of the current regulations, a standard design certification continues to be effective in a hearing for a combined license or operating license docketed before the expiration date, and in a hearing under § 52.103 for authority to load fuel and operate. At minimum, the original standard design certification applicant should be subject to Section 206 requirements until the proceeding is completed. Beyond the minimum requirements, the NRC also believes that the original design

certification applicant's Section 206 obligations should continue until operation is no longer authorized in accordance with § 50.82(a)(2) for the last operating license or combined license referencing that standard design certification. The NRC believes that the regulatory need for information concerning defects in a standard design certification continues throughout the operating life of a license referencing that design certification; the relevance of and the NRC's need for this information, if subsequently discovered by the original design certification applicant, does not diminish simply because the standard design certification may no longer be referenced.

Second principle - Notification occurs when information is needed.

The second principle is focused on ensuring that the NRC, its licensees, and license applicants receive information on defects at the time when the information would be most useful to the NRC in carrying out its regulatory responsibilities under the AEA, and to the licensee or applicant when engaging in activities regulated by the NRC. A result of this principle is that reporting may be delayed if there is no immediate consequence or regulatory interest in prompt reporting, and that delayed reporting will actually occur when necessary to support effective, efficient, and timely action by the NRC, its licensees and applicants. Applying the second principle and its result to part 52 processes, the NRC believes that immediate reporting is required throughout the period of pendency of an application - be it a license, a standard design approval or a standard design certification. Allowing an applicant to delay the reporting of a defect would appear to be inconsistent with the NRC's statutory mandate to provide adequate protection to public health and safety and common defense and security. Even if delayed reporting would allow the NRC an opportunity to modify its prior safety finding with respect to the license, design approval or design certification, the delayed consideration is inconsistent

with one of the fundamental purposes of part 52, *viz.*, to provide for early consideration and resolution of issues in a manner that avoids the potential for delay during licensing of a facility. Accordingly, the NRC's view is that the NRC's reporting requirements implementing Section 206 of the ERA must extend to applicants (and their contractors and subcontractors) for all part 52 processes (licenses, early site permits, design approvals, and design certifications). Once an application has been granted, the NRC believes that immediate reporting of subsequently-discovered defects is not necessary in certain circumstances. For those part 52 processes which do not authorize continuing activities required to be licensed under the AEA, but are intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals, the NRC believes that reporting of defects or failures to comply associated with substantial safety hazards may be delayed until the time that the part 52 process is first referenced. The NRC's view is based upon its determination that a defect with respect to part 52 processes should not be regarded as a "substantial safety hazard," because the possibility of a substantial safety hazard becomes a tangible possibility necessitating NRC regulatory interest only when those part 52 processes are referenced in an application for a license, early site permit, design approval or design certification. Upon initial referencing, the holder (or in the case of a design certification), the applicant who submitted the application leading to the final design certification regulation must make the necessary notifications to the NRC as well as provide final engineering. The notification must address the period from the Commission adoption of the final design certification regulation up to the filing of the application referencing the final design certification regulations. Thereafter, notice must be made in the ordinary manner. The notification obligation ends when the last license referencing the design certification is terminated.

Third principle - Procedures and practices must be implemented to ensure accurate and timely reporting.

The third principle (*viz.*, each entity conducting activities under the purview of part 52, should develop and implement procedures and practices to ensure that the entity accurately and timely fulfils its reporting obligation as delineated in the NRC's regulations), is intended to ensure the effectiveness of each entity's reporting processes. This is especially true where there is a potential for substantial passage of time between the discovery of a defect and the reporting of the defect, as may be allowed by the NRC consistent with the second principle. For example, following issuance of a final standard design certification regulation, if the original applicant determines that there is a substantial safety hazard, that applicant need not report the discovery until the time that the design certification rule is referenced - which may be as long as 15 years from the date of the final rule. Given the substantial time that may pass between the time of discovery and the date of reporting, it is imperative that the original standard design certification applicant develop and implement procedures from the time of effectiveness of the final design certification regulations.

The result of the third principle, consistent with part 21's current requirements, is that licensees, license applicants, and other entities seeking a design approval or design certification, must have contractual provisions with their contractors, subcontractors, consultants and other suppliers which notify them that they are subject to the NRC's regulatory requirements on reporting and the development and implementation of reporting procedures. This result is currently reflected in § 21.31; the NRC proposes to add the corresponding requirement to § 50.55(e)(7).

Division of implementing requirements between Part 21 and § 50.55(e).

Under the Commission's current regulatory structure, persons and entities engaged in construction (or the functional equivalent of construction) are subject to reporting requirements under § 50.55(e). Persons and entities engaged in all other activities within the purview of Section 206 of the ERA are subject to the requirements in part 21 and/or § 50.55(e). The proposed changes to part 21 and § 50.55(e) reflect the NRC's determination to retain this divided regulatory structure. The NRC believes that the only part 52 processes that authorize "construction" or its functional equivalent are manufacturing licenses and combined licenses before the Commission makes the finding under § 52.103(g). Therefore, the proposed reporting requirements with respect to Section 206 of the ERA for manufacturing licenses and combined licenses before the Commission makes the finding under § 52.103(g) are contained in § 50.55(e). The requirements in part 21 apply after the Commission makes the finding § 52.103(g) for a combined license. Part 21 would be revised to explicitly apply to the remaining part 52 processes, i.e., early site permits, standard design approvals, and standard design certifications. Table A-1 provides a summary of the NRC's proposed applicability of part 21 and § 50.55(e) to each of the various approvals under part 52. The NRC requests comments on whether the existing division between part 21 and § 50.55(e) should be maintained, or whether the substantive requirements of § 50.55(e) should be incorporated into part 21, with § 50.55(e) (and/or perhaps another regulation in part 50) setting forth a cross-reference to part 21. Note that one of the principle differences between part 21 and § 50.55(e) is that § 50.55(e)(1)(iii)(C) requires reporting of QA breakdowns in addition to defects and failures to comply associated with substantial safety hazards. The other is that the requirement governing commercial grade dedication is only found in part 21.

Reporting requirements for early site permits.

If the early site permit holder becomes aware of a significant safety concern with respect to its site (e.g., that the specified site parameter for seismic acceleration is less than the projected acceleration due to new information), the concern should be reported to the NRC so that it may be considered in the review of any future application referencing the early site permit. This reporting attains special importance given the NRC's proposal not to impose an updating requirement for early site permit information other than that related to emergency preparedness. In order for the applicant for an early site permit to have the capability to report to the NRC any known significant safety concerns with respect to its site, or any safety concerns of which it may subsequently become aware (i.e., to be able to report any defects or failures to comply associated with substantial safety hazards under part 21) the early site permit applicant would have to have a program in place for implementing the requirements of 10 CFR part 21. The applicant's program may be inspected by the NRC as part of the application review and approval of the early site permit application would be subject to approval of the part 21 program.

Table A-1

**Applicability of NRC Requirements Implementing Section 206 of the Energy Reorganization Act
to Part 52 Licensing and Approval Processes**

Part 52 Licensing or Approval Processes	Applicable NRC Requirement implementing Section 206 of the ERA	Sanctions	
		Civil	Criminal
Early Site Permit (ESP) Subpart A			
Application *	part 21	21.61	21.62
Issuance of ESP	part 21	21.61	21.62
Standard Design Approval (SDA) Subpart E			
Application *	part 21	21.61	21.62
Issuance of SDA	part 21	21.61	21.62
Standard Design Certification Rule (DCR) Subpart B			
Application *	part 21	21.61	21.62
Final DCR rulemaking	part 21	21.61	21.62
Combined License (COL) Subpart C			

Application *	50.55(e)	50.110	50.111
COL before § 52.103 authorization	50.55(e)	50.110	50.111
COL after § 52.103 authorization	part 21	21.61	21.62
Manufacturing License (ML) Subpart F			
Application *	50.55(e)	50.110	50.111
Issuance of ML	50.55(e)	50.110	50.111

* Currently, there is no explicit requirement imposing part 21 on an applicant for a construction permit (CP). However, as a practical matter the NRC has required these applicants to implement a part 21 program before approval of the CP. The Commission proposes to take the same approach with respect to applicants for a COL, DCR, ESP, FDA, or ML.

Applicability of Part 21 to contractors or subcontractors of an ESP applicant or holder.

In accordance with 10 CFR 21.31, the purchaser of a basic component must state in the procurement documents for the basic component that part 21 is applicable to that procurement. As explained above, services that are required to support an early site permit application (e.g., geologic or seismic analyses, etc.) that are safety-related and could be relied upon in the siting, design, and construction of a nuclear power plant, are to be treated as basic components as defined in part 21. Therefore, these services must be either purchased as basic components, requiring the service provider to have an appendix B to part 50 QA program, as well as its own part 21 program, or the early site permit applicant could dedicate the service in accordance with part 21 and the standard review plan, which requires the dedication process itself to be controlled under an appendix B to part 50 QA program.

Reporting requirements for standard design approvals.

A standard design approval represents the NRC staff's determination regarding the acceptability of the design for a nuclear power reactor (or major portions thereof). Although a standard design approval does not represent the NRC's final determination as to the acceptability of the design, it nonetheless represents a substantial expenditure of agency resources in reviewing the design. A standard design approval may be referenced in a subsequent application for a design certification, construction permit, operating license, combined license, or manufacturing license. Accordingly, consistent with the first principle, the NRC proposes to impose requirements implementing Section 206 of the ERA on applicants for and holders of standard design approvals.

A standard design approval does not authorize construction of a nuclear power plant; it merely constitutes the NRC staff 's approval of the design of a nuclear power reactor (or major portion thereof). Therefore, the NRC proposes that the requirements implementing Section 206 of the ERA, which are applicable to standard design approvals, be placed in part 21, as opposed to § 50.55(e).

Reporting requirements for standard design certification regulations.

A standard design certification represents the NRC's approval by rulemaking of an acceptable nuclear power reactor design, which may then be referenced in a subsequent combined license or manufacturing license application. Consistent with the first principle, the Commission proposes to impose Section 206 of the ERA reporting requirements on applicants for design certifications, including applicants whose designs are certified in a final design certification rulemaking. As with a standard design approval, a design certification does not actually authorize construction. Accordingly, the NRC proposes to revise §§ 21.3, 21.21, 21.51, and 21.61 to explicitly refer to an applicant for a standard design certification, rather than to revise § 50.55(e).

Some industry stakeholders have asserted that because there is no "holder" or licensee, the NRC is without authority under Section 206 of the ERA to impose part 21 and/or § 50.55(e) evaluation and reporting requirements on applicants for standard design certification. The NRC disagrees with this assertion. The statute by its terms does not limit its reach to licensees; rather, the statute applies to any individual or responsible officer of a firm "construction, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated" The NRC believes that an applicant for a standard design certification, by submitting its application, is constructively "supplying" a "component" (the nuclear power

reactor) for use in a future “facility...licensed” by the NRC. One of the consequences of the design certification provisions in part 52 is the ability of the applicant to subsequently offer its design with additional, value-added services. Thus, applying for and facilitating NRC adoption of a final standard design certification regulation is simply a partial step in the overall activity of “supplying” the certified design to potential nuclear power plant license applicants. Alternatively, one could treat the standard design certification applicant as supplying a component of an “activity” which is “otherwise regulated” by the NRC. Under this interpretation, the “activity...otherwise regulated by the NRC” can be viewed as the design certification rulemaking, and/or the entire part 52 regulatory regime whereby a design certification rule is referenced in a subsequent licensing application. The NRC concludes that under either interpretation, Section 206 of the ERA provides ample statutory authority for the NRC to impose regulations implementing Section 206 on design certification applicants, during the pendency of the application before the NRC, as well as after NRC adoption of a final design certification regulation (for those applicants whose application is granted).

As with standard design approvals, a standard design certification does not authorize construction of a nuclear power plant; it constitutes the NRC’s approval of the design of a nuclear power reactor. Therefore, the NRC proposes that the requirements implementing Section 206 of the ERA which are applicable to standard design certifications be placed in part 21, as opposed to § 50.55(e).

Reporting requirements for combined licenses.

A combined license authorizes both construction of a nuclear power plant, and loading of fuel and operation if the NRC makes the findings specified in § 52.103. As such, the application of the first and second principles to combined licenses is the most straightforward of

all the part 52 processes. Under the proposed rule, the NRC's requirements implementing Section 206 of the ERA would apply throughout the regulatory life of the combined license, i.e., from docketing of the application until termination of the combined license.

To maintain the current division between § 50.55(e) and part 21 with respect to NRC requirements implementing Section 206 of the ERA, the NRC proposes to revise § 50.55(e) to make its provisions applicable to each holder of a combined license under part 52 before the effective date of the NRC's authorization of fuel load and operation under § 52.103, and to revise part 21 to clarify that its provisions apply to each holder of a combined license on the effective date of the Commission's authorization under § 52.103.

Reporting requirements for manufacturing licenses.

Under proposed Part F of part 52, a manufacturing license would constitute both the NRC's approval of a final nuclear power reactor design, as well as approval to manufacture one or more reactors in accordance with approved programs and procedures. The manufactured reactors would then be transported offsite and incorporate nuclear power facilities by holders of combined licenses - who may be different entities than the holder of a manufacturing license. Given the possibility that the manufacturing license holder is different from the combined license holder whose facility uses the manufacturing license, the NRC believes that the combined license holder using the manufactured reactor must be kept informed of any significant issue with design or manufacture of the reactor, to ensure that they evaluate the significance of these matters for their facility and undertake any necessary action to assure public health and safety and common defense and security. Furthermore, unlike a standard design certification, the financial resources necessary to obtain a manufacturing license will, as a practical matter, result in manufacturing beginning immediately after issuance of the manufacturing license. There will

be no interim period similar to a design certification where there is no activity occurring under the manufacturing license. Accordingly, in compliance with the first and second principles, the NRC proposes that Section 206 of the ERA requirements should apply continuously from the filing of the application, until the manufacturing license expires or is otherwise terminated by the NRC.

A manufacturing license holder would essentially be conducting the same activities as a construction permit holder, albeit with several differences.⁶ Nonetheless, the NRC believes that manufacturing is similar to construction such that the NRC's requirements implementing Section 206 of the ERA which are applicable to manufacturing licenses, should be contained in § 50.55(e). Accordingly, the NRC proposes to revise § 50.55(e) to specifically apply its provisions to holders of manufacturing licenses.

K. Proposed Change to 10 CFR Part 25.

1. Section 25.5, *Definitions* and Section 25.35, *Classified visits*.

Part 25, which sets forth the NRC's requirements governing the granting of access authorization to classified information to certain individuals, does not currently reflect the licensing and approval processes in part 52. Accordingly, the NRC proposes to make several changes to ensure that individuals who seek a license, standard design approval, or standard

⁶These key differences are, first, the design of the manufactured plant would be approved before manufacturing commences, unlike the historical practice with construction permits. Second, a single manufacturing license may authorize the manufacture of multiple reactors, with the manufacturing process to be accomplished in a controlled setting rather than as a "field" operation. This is unlike the historical approach where non-standardized nuclear power facilities were constructed onsite using a "roving" workforce. Third, the manufacturing license will specify the inspections, tests, and acceptance criteria for determining successful manufacturing.

design certification under part 52 and require access authorization, are subject to the provisions of part 25. Because part 52 involves entities other than licensees, the NRC proposes to revise the title of part 25 to simply read, "Access Authorization." The NRC also proposes to revise § 25.35 to refer to an applicant for a standard design certification under part 52 (including the applicant after the NRC adopts a final standard design certification rule), and the applicant for or holder of a standard design approval under part 52.

L. Proposed Changes to 10 CFR Part 26.

1. Section 26.2, Scope, Section 26.10, *General performance objectives*; and Appendix A to Part 26

Part 26, which sets forth the NRC's requirements governing fitness-for-duty, currently uses a two-part regulatory regime for the application of fitness-for-duty requirements. A holder of an operating license for a nuclear power plant is required to implement all of the provisions in part 26. By contrast, a holder of a construction permit is required to implement a subset of part 26 requirements - §§ 26.10, 26.20, 26.23, 26.70, and 26.73 - which excludes the drug testing provisions in part 26.

The NRC proposes to extend the applicability of parts 26 to 52, in keeping with the existing two-part regulatory regime, so that the full array of requirements in part 26 apply to a combined license holder after the date that the NRC authorizes fuel load and operation under § 52.103, analogous to holder of an operating license under part 50. By contrast, holders of combined licenses, before the date that the NRC authorizes fuel load and operation would be required to comply with the more limited set of part 26 provisions currently applicable to construction permit holders. Similarly, holders of manufacturing licenses under subpart F of

part 52 would be treated the same as holders of construction permits. Finally, persons authorized to conduct the limited construction activities allowed under § 50.10(e)(3) would also be treated the same as a construction permit holder. The proposed rule would accomplish this by: (1) revising § 26.2(a) to refer to combined license holders after the date that the NRC authorizes fuel load and operation under § 52.103; (2) revising § 26.2(c) to refer to a holder of a combined license before the date that the NRC makes the finding under § 52.103(g), a holder of a manufacturing license under subpart F of part 52, and a person authorized to conduct the activities under § 50.10(e)(3); (3) revising § 26.10(a) to refer to the personnel of a holder of a manufacturing license and those authorized to conduct the activities under § 50.10(e)(3); and (4) revising appendix A to part 26, paragraph 1.1(1) to include a reference to a holder of combined license after the date that the NRC makes the finding under § 52.103(g).

The NRC believes that part 26 need not be extended to cover applicants for and holders of early site permits, standard design approvals, and applicants for standard design certifications under part 52. These activities present less of a concern with respect to public health and safety, and common defense and security, as compared with construction permits, manufacturing licenses, operating licenses and combined licenses. None of these regulatory approvals or design certification regulations authorize the construction, manufacture, or operation of a facility, nor do they authorize possession of special nuclear material (SNM). The adverse impacts on public health and safety or common defense and security attributable to any fitness-for-duty issues are likely to be of a much lower level of significance, as compared to issues that may occur during construction, manufacture, operation, or possession of SNM. The NRC believes that the potential benefits of imposing the fitness-for-duty requirements are not justified in view of the regulatory burden to be imposed upon such applicants and holders. Accordingly, the proposed rule would not be imposed on applicants for and holders of standard design approvals, and applicants for standard design certifications under part 52.

M. Proposed Changes to 10 CFR Part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.

The proposed rule would make several conforming changes to part 51 to clarify the environmental protection regulations applicable to the various part 52 licensing processes.

NEPA Compliance for Design Certifications.

For each of the three design certification rules in Appendices A, B, and C of part 52, as well as the proposed design certification rule for the AP1000 design, the NRC prepared an environmental assessment which: (1) provides the bases for a Commission finding of no significant environmental impact (FONSI) for issuance of the design certification regulation; and (2) identifies and addresses the need for incorporating severe accident mitigation design alternatives (SAMDA) into the design certification rule. Based upon this experience, the NRC proposes to make changes to part 51 to accomplish two objectives.

First, the NRC proposes to eliminate the need for the NRC to prepare essentially repetitive discussions in environmental assessments supporting a FONSI on issuance of a final standard design certification regulation. Each of the environmental assessments and FONSIs prepared to date conclude that there is no significant environmental impact associated with NRC issuance of a final design certification regulation because a design certification does not authorize either the construction or operation of a nuclear power facility. Design certification represents the NRC's pre-approval of the design for the nuclear power facility, but does not authorize manufacture or construction. For the design certification to have practical effect, it must be referenced in an application for a combined license. Therefore, the environmental effects of construction and operation of a nuclear power facility using the referenced design

certification are to be addressed in the environmental impact statement (EIS) for the combined license. This is practical inasmuch as the full scope and details of the benefits and environmental impacts of constructing and operating a nuclear power reactor using the design approved in the design certification are most likely known at the time when the design certification is proposed to be used in a specific nuclear power facility at a particular site; this rationale will remain the same for all future design certifications. The NRC proposes to revise part 51 to eliminate the need for the NRC to make repetitive findings of no significant environmental impact for future design certifications and amendments to design certifications.

Second, the NRC proposes to require that SAMDAs be addressed at the design certification stage. SAMDAs are alternative *design* features for preventing and mitigating severe accidents, which may be considered for incorporation into the proposed design; the SAMDA analysis is that element of the SAMDA analysis dealing with design and hardware issues. At the design certification stage, the NRC's review is directed at determining if there are any cost beneficial SAMDAs that should be incorporated into the design, and if it is likely that future design changes would be identified and determined to be cost-justified in the future based on cost/benefit considerations. It is most cost effective to incorporate SAMDAs into the design at the design certification stage. Retrofitting a SAMDA into a design certification once site-specific design and engineering for a nuclear power facility has increased the cost of implementing a SAMDA. The retrofitting costs continue to increase in ensuing stages of facility construction and operation. For these reasons, the NRC believes that environmental assessments for design certifications should address SAMDAs. However, under the current provisions of part 51, both the environmental information submitted by the design certification applicant, and the environmental assessment prepared by the NRC, are directed either at determining whether an EIS must be prepared, or that a FONSI is justified. Accordingly, the

NRC proposes that SAMDAs be addressed in environmental reports and environmental assessments for design certifications.

The NRC proposes to make a number of changes to accomplish these two objectives. Existing § 51.55 would be redesignated as § 51.58, and § 51.55 would be added to indicate that an environmental report submitted by the design certification applicant must be directed towards addressing the costs and benefits of possible SAMDAs, and presenting the bases for not incorporating identified SAMDAs into the design to be certified. The environmental report for an applicant seeking to amend an existing design certification would be somewhat narrower by focusing on if the design change which is the subject of the amendment, renders a SAMDA previously rejected to become cost-beneficial; and if the design change results in the identification of new SAMDAs that may be reasonably incorporated into the design certification.

Section 51.30 would be revised to provide for a new § 51.30(d) establishing the scope of an environmental assessment for a design certification. Section 51.32 (b)(1) and (2) would be added to set forth the NRC's generic determination of no significant environmental impact associated with issuance of a final or amended design certification rule. This is, essentially, the legal equivalent of a categorical exclusion. The NRC proposes to include an explicit statement of no significant environmental impact in § 51.32. The NRC believes that external stakeholders will better understand the nature of the Commission's action by doing so. Section 51.31 would be modified by adding § 51.30(b) specifying the information on the environmental assessment to be included in the proposed rulemaking on the design certification published in the *Federal Register*.

Section 51.50(c)(2) would be revised to indicate that if a combined license application references a design certification then the combined license applicant's environmental report may reference the SAMDA discussion in the design certification environmental assessment as part of its SAMDA analysis, but must contain information demonstrating that the site

characteristics for the combined license site falls within the site parameters in the design certification environmental assessment.⁷

Finally, § 52.75(c)(2) would be added to provide that if a combined license application references a design certification, then the combined license EIS will incorporate by reference the design certification environmental assessment, and summarize the SAMDA analysis and conclusions of the environmental assessment.

NEPA Compliance for Manufacturing Licenses.

The NRC believes that its current approach for meeting the Commission's NEPA responsibilities for standard design certifications should be extended to manufacturing licenses for nuclear power reactors. Under proposed subpart F to part 52, a manufacturing license is similar to a standard design certification in that a final nuclear power reactor design would be approved. Therefore, the NRC proposes that the environmental effects of construction and operation of a nuclear power facility using a manufactured reactor would be addressed in the EIS for the combined license application for a nuclear power facility using a manufactured reactor, rather than in an environmental assessment or EIS at the manufacturing license stage.

Further, the NRC does not believe that NEPA requires the NRC to address the environmental impacts of actually manufacturing a nuclear power reactor licensed under subpart F of part 52, either at the manufacturing license stage or at the combined license stage where an application proposes to use a manufactured reactor. The manufacturing license

⁷The design certification applicant may have chosen to specify site parameters for the design certification safety review under § 52.79 which differ from the site parameters specified in the environmental report for its design. If such a design certification is referenced in a combined license application, the combined license applicant must demonstrate that the two differing sets of site parameters are met, in order for the full panoply of issue finality provisions in § 52.63 to apply in the combined license proceeding.

approves the final design of the manufactured reactor, the organization and technical procedures for designing and manufacturing the reactor, and the ITAAC that are to be used by the licensee in determining whether the reactor has been properly manufactured in accordance with NRC requirements and the manufacturing license, and the possession (but not the use or transport offsite) of the manufactured reactor. The manufacturing license does not approve any specific location, building, or facility where the actual manufacture of the reactors may occur,⁸ and the NRC does not require the applicant for the manufacturing license to submit any information on these matters as part of its application. These matters are commercial matters generally unrelated to the NRC's regulatory jurisdiction. The Federal Aviation Administration (FAA) does not prepare an EIS when issuing a production certificate under 14 CFR part 21, subpart G, authorizing the production of an aircraft or component in conformance with a type certificate. See Federal Aviation Agency Order 1050.1E, Sec. 308c (June 8, 2004). Because the NRC does not approve any specific location or facility in which to manufacture any component of or the reactor licensed under the manufacturing license, it would be speculative for the NRC to describe and assess the environmental impacts of manufacturing. NEPA does not require that an EIS address speculative impacts. The NRC also notes that EISs prepared in the past for construction permits and operating licenses under part 50, as well as current environmental assessments for nuclear power plant license amendments, have never considered the offsite environmental impacts of fabricating systems and components by vendors and subcontractors, even for circumstances where the fabrication activities are subject to NRC regulatory jurisdiction (e.g., under applicable provisions of parts 19 and 21). For these reasons, the NRC concludes that NEPA does not require the NRC to address, either at the

⁸A reactor manufactured outside of the United States would not be within the scope of a manufacturing license under subpart F of part 52, by virtue of proposed § 52.9, which states that no license shall be deemed to have been issued for activities which are not under or within the jurisdiction of the United States.

manufacturing license stage or at the combined license stage where the application proposes to use a manufactured reactor, the speculative impacts of manufacturing a reactor offsite at a location or in a facility not specified or approved in the manufacturing license.

The NRC proposes to make a number of changes to part 51, in some cases parallel to those described above with respect to design certifications, consistent with its views on manufacturing licenses. Existing § 51.54 would be revised to clarify that an environmental report for a manufacturing license must address the costs and benefits of SAMDAs and the bases for not incorporating SAMDAs into the design of the reactor to be manufactured, and to state that the environmental report need not address the impacts of manufacturing a reactor under the manufacturing license. Section 51.20(b)(6), which currently requires preparation of an EIS for issuance of a manufacturing license, and § 51.76, which currently addresses the subject matter of an EIS for a manufacturing license, would both be removed from part 51.

Section 51.30(e) would be revised to establish the scope of an environmental assessment prepared for a manufacturing license. Section 51.32(b)(3) and (4) would be added to state the NRC's generic determination of no significant environmental impact associated with issuance of a final or amended manufacturing license. As with the parallel provisions governing design certifications in § 50.32(b)(1) and (2), the NRC proposes to include an explicit statement of no significant environmental impact for manufacturing licenses in § 51.32(b)(3) and (4) to facilitate external stakeholder's understanding of the nature of the Commission's action. Section 51.31(c) would be added to describe the NRC's process for determining the manufacturing license with respect to environmental issues covered by NEPA.

Section 51.50(c)(3) would be added to provide that if a combined license application proposes using a manufactured reactor, then the combined license environmental report may incorporate by reference the environmental assessment for the manufacturing license under which the reactor is to be manufactured and, if so, must include information demonstrating that

the site characteristics for the combined license site fall within the site parameters specified in the manufacturing license environmental assessment. This section also would state that the environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

Finally, § 51.75(c)(3) would be added to indicate that if the combined license application proposed to use a manufactured reactor and the site characteristics of the combined license's site fall within the site parameters specified in the manufacturing license environmental assessment,⁹ then the combined license EIS must incorporate by reference the manufacturing license environmental assessment. As in the case where the combined license application references a design certification, § 52.75(c)(3) requires the combined license EIS to summarize the findings and conclusions of the environmental assessment with respect to SAMDAs. Finally, § 51.75(c)(3) would explicitly provide that the combined license EIS will not address the environmental impacts of manufacturing the reactor under the manufacturing license.

NEPA obligations associated with § 52.103(g) findings on ITAAC.

Currently, neither part 51 nor subpart C of part 52 explicitly address whether an environmental finding under NEPA is needed in connection with an NRC finding under § 52.103(g) that combined license ITAAC have been met. Nor does part 51 or subpart C of part 52 explicitly address whether contentions on environmental matters may be admitted in a hearing under § 52.103(b). The NRC never intended to make an environmental finding in

⁹Analogous to design certifications, it is possible that an applicant for a manufacturing license may have chosen to specify site parameters for the manufacturing license safety review under § 52.79 which differ from the site parameters specified in the environmental report for its design. If the combined license application proposes to use such a manufactured reactor, then the combined license applicant must demonstrate that the two differing sets of site parameters are met, in order for the full division of issue finality provisions in § 52.171 to apply in the combined license proceeding.

connection with the § 52.103(g) finding on ITAAC, and the NRC does not believe that NEPA requires such a finding. The § 52.103(g) finding that ITAAC have been met is not a “major Federal action significantly affecting the environment.” The major Federal action occurred when the NRC issued the combined license, which included the authority to operate the nuclear power plant - subject to an NRC finding of successful completion of ITAAC. This is the reason why the environmental impacts of operation under the combined license are evaluated and considered by the NRC in determining whether to issue the combined license even under the current provisions of part 52, see § 52.89. By contrast, the scope and nature of the NRC finding that ITAAC have been met is constrained by the ITAAC itself (indeed, the NRC has always recognized the possibility that ITAAC could be written such that the “inspections and tests” exception in Section 554(a)(3) of the APA could be invoked to preclude the need to provide an opportunity for hearing on § 52.103(g) findings). The safety consequences of operation are not considered when making the § 52.103(g) findings; these issues are addressed by the NRC in determining whether to issue the combined license in the first place. Therefore, the NRC does not view the § 52.103(g) finding as constituting a “major Federal action,” and makes no environmental findings in connection with that finding. It, therefore, follows that no contentions on environmental matters should be admitted in any hearing under § 52.103(b).

Accordingly, the NRC proposes adding § 51.108 to clarify that: (1) the Commission will not make any environmental findings in connection with the finding under § 52.103(g); and (2) contentions on any environmental matters, including the adequacy of the combined license EIS and any referenced environmental assessment, may not be admitted into any § 52.103(b) hearing on compliance with ITAAC. Those issues are essentially challenges to the continuing validity of the combined license or any referenced design certification, early site permit, or manufacturing license. Accordingly, these challenges should be raised with the Commission using relevant Commission-established processes for requesting Commission action. A

challenge on environmental grounds with respect to the combined license, early site permit, or manufacturing license must be filed under the provisions of § 2.202. A challenge to an existing design certification on environmental grounds must be filed as a petition for rulemaking to modify the existing design certification under subpart H of part 2.

More specific changes to individual sections in part 51 are discussed below.

Section 51.20, Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

Section 51.20(b) would be revised to identify the part 52 licensing processes that require an environmental impact statement or a supplement to an environmental impact statement. Specifically, § 51.20(b)(1) would be revised to indicate that issuance of an early site permit requires an EIS. Section 51.20(b)(2) would be revised to indicate that issuance of a combined license requires an EIS. Also, paragraph (b)(6) would be removed and reserved because, under the Commission's proposed revision to the requirements for manufacturing licenses, only an environmental assessment is required at this stage.

Section 51.22, Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

Section 51.22(c) would be revised to identify part 52 licensing processes that are eligible for categorical exclusion or otherwise don't require environmental review.

Section 51.23, *Temporary storage of spent fuel after cessation of reactor operation—generic determination of no significant environmental impact.*

Sections 51.23(b) and(c) would be revised to indicate that the provisions of these paragraphs also apply to combined licenses.

Section 51.45, *Environmental report.*

Section 51.45(c) would be revised to indicate that the analysis in an environmental report prepared for an early site permit need not include consideration of the economic, technical, and other benefits and costs of the proposed action and of energy alternatives. This change is proposed for consistency with the provisions of § 52.17(a)(2), which states that an environmental report included in an early site permit application need not include an assessment of the benefits (for example, need for power) of the proposed action and the Commission's denial of a Petition for Rulemaking (See PRM-52-02 (October 28, 2003; 68 FR 55905)).

Section 51.50, *Environmental report—construction permit, early site permit, or combined license stage.*

The proposed rule would revise the title of § 51.50 to “Environmental report—construction permit, early site permit, or combined license stage,” and include separate paragraphs with specific requirements for environmental reports for early site permit and combined license applications which are based on existing requirements in part 51 for

construction permits and operating licenses and requirements for early site permits and combined licenses in part 52.

Where a combined license applicant is referencing an early site permit, the NRC staff is proposing to add a requirement in § 51.50 that the applicant's environmental report need not contain information or analyses submitted to the Commission in the early site permit stage, but must contain, in addition to the environmental information and analyses otherwise required: (1) information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit; (2) information to resolve any other significant environmental issue not considered in the early site permit proceeding, either for the site or design; and (3) any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit EIS. The NRC staff is also proposing to add a requirement that the applicant must have a reasonable process for identifying any new and significant information regarding the NRC's conclusions in the early site permit EIS.

The NRC's regulations and the applicable case law interpreting the National Environment Policy Act of 1969, as amended (NEPA), support the NRC staff's belief that, inasmuch as an early site permit and a combined license are major Federal actions significantly affecting the quality of the human environment, both actions require the preparation of an EIS. However, 10 CFR part 52 does provide finality for previously resolved issues. Under NEPA, the combined license environmental review is informed by the EIS prepared at the early site permit stage and the NRC staff intends to use tiering and incorporation-by-reference whenever it is appropriate to do so. The combined license applicant must address any other significant environmental issue not considered in any previous proceeding, such as issues deferred from the early site permit stage to the combined license stage (e.g., the benefits assessment).

For an early site permit, the NRC prepares an EIS that resolves numerous issues within certain bounding conditions. These issues are candidates for issue preclusion at the combined license, CP or OL stage. If the issue could be deferred and the combined license applicant elected to do so, e.g., the benefits assessment, then the combined license applicant would be required to address the issue in its combined license, CP, or OL application. A combined license, CP, or OL application must also demonstrate that the design of the facility falls within the parameters specified in the early site permit. In addition, the application should indicate whether the site is in compliance with the terms of the early site permit. The information supporting a conclusion that the site is in compliance with the early site permit should be maintained in an auditable form by the applicant. While the NRC is ultimately responsible for completing any required NEPA review, for example, to ensure that the conclusions for a resolved early site permit environmental issue remain valid for a combined license action, the combined license applicant must identify whether there is new and significant information on such an issue. A combined license applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form for issues for which the combined license applicant does not identify any new and significant information.

Under 10 CFR 51.70(b), the NRC is required to independently evaluate and be responsible for the reliability of all information used in the EIS, including an EIS prepared for a combined license. In carrying out its responsibilities under 10 CFR 51.70(b), the NRC staff may (1) inquire into the continued validity of information disclosed in an EIS for an early site permit that is referenced in a combined license application; and (2) look for any new information that may affect the assumptions, analysis, or conclusions reached in the early site permit EIS.

The initial burden to assess newly identified information and those issues that were deferred to the combined license, CP, or OL application falls to the applicant. The applicant is

required to provide information sufficient to resolve any other significant environmental issue not considered in the early site permit proceeding, either for the site or design, and the information contained in the application should be sufficient to aid the staff in its development of an independent analysis (see 10 CFR 51.45). Therefore, the environmental report must contain new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit EIS.

The NRC staff, in the context of a combined license application that references an early site permit, defines “new” in the phrase “new and significant information” as any information that was not contained or referenced in the early site permit application or the early site permit EIS. This new information may include (but is not limited to) specific design information that was not contained in the application, especially where the design interacts with the environment, or information that was in the early site permit application, but has changed by the time of the combined license application. This new information may or may not be significant.

In the past, the NRC staff has attempted to explain the relationship between the environmental review of an early site permit application to that of a combined license application referencing the early site permit by analogy to the license renewal environmental review process. The NRC staff believes the analogy especially useful because the license renewal process is well-established and clearly understood. Because there appears to be some confusion regarding this analogy, NRC believes a brief explanation of the similarities of the two processes is warranted.

For license renewal, the NRC prepared a generic EIS (GEIS) that resolved more than 60 issues for all plants based on certain bounding assumptions; these were termed Category 1 issues. If a license renewal applicant identifies new and significant information with respect to a Category 1 issue, it documents its assessment of that information in its application. If the applicant determines that this new information is not significant, or that there is no new

information, the applicant documents the bases for these determinations in an auditable form and makes the documentation available for staff inspection. If there is new and significant information on a Category 1 issue, the NRC staff limits its inquiry to determine if this information changes the Commission's earlier conclusion set forth in the GEIS. The NRC staff may inquire if the applicant has a reasonable process for identifying new and significant information on Category 1 issues.

Similarly, in the NRC environmental review process for a combined license application, the combined license EIS brings forward the Commission's earlier conclusions from the early site permit EIS and articulates the activities undertaken by the NRC staff to ensure that an issue that was resolved can remain resolved. If there is new and significant information on a previously resolved issue, then the staff will limit its inquiry to determine if the information changes the Commission's earlier conclusion. Environmental matters subject to litigation in a combined license proceeding mainly include (1) those issues that were not considered in the previous proceeding on the site or the design; (2) those issues for which there is new and significant information; and (3) those issues subject to the change or exemption processes in 10 CFR part 52.

Notwithstanding that, in the context of renewal, the GEIS resolves Category 1 issues through rulemaking and an early site permit resolves environmental issues through an individual licensing proceeding, the staff believes that the license renewal practice is similar to the part 52 process in which a combined license application references an early site permit.

In conclusion, the NRC staff has determined that a combined license is a major Federal action significantly affecting the quality of the human environment and, in accordance with 10 CFR 51.20, the NRC must prepare an EIS on that action. For matters resolved at the ESP stage, if there is no new and significant information that differs from that discussed in the ESP EIS, then the staff will rely upon ("tier off") the early site permit EIS and disclose the NRC

conclusion for matters covered in the early site permit review. Such matters will not be subject to litigation at the combined license stage.

Section 51.51, *Uranium fuel cycle environmental data—Table S-3.*

Section 51.51 would be revised to require that every environmental report prepared for the early site permit stage or combined license stage of a light-water-cooled nuclear power reactor use Table S-3, Table of Uranium Fuel Cycle Environmental Data, as the basis for evaluating the contribution of the environmental effects of the uranium fuel cycle to the environmental costs of licensing light-water cooled nuclear power reactors.

Section 51.52, *Environmental effects of transportation of fuel and waste—Table S-4.*

Section 51.52 would be amended to require that every environmental report prepared for the early site permit stage or combined license stage of a light-water-cooled nuclear power reactor contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor.

Section 51.53, *Postconstruction environmental reports.*

Section 51.53(a) would be revised to clarify that any postconstruction environmental report may incorporate by reference any information contained in a prior environmental report or supplement thereto that relates to the site or any information contained in a final environmental document previously prepared by the NRC staff that relates to the site. This change reflects the

recognition that environmental documents will be prepared at the early site permit stage and may be referenced in environmental documents for future licensing actions. Section 51.53(a) also would be revised to clarify that documents that may be referenced in post construction environmental reports include those prepared in connection with an early site permit or a combined license. In addition, § 51.53(c)(3) would be revised to clarify that the requirements for the content of environmental reports submitted in applications for renewal of a combined license are the same as those for renewal of an operating license.

Section 51.54, *Environmental report—manufacturing license.*

The proposed rule would amend this section by adding two paragraphs to delineate the difference in the matters with respect to SAMDAs that must be addressed in an environmental report for issuance of a manufacturing license under subpart F of part 52, versus that for an amendment to the manufacturing license. Section 51.54(a) provides that the environmental report for the manufacturing license must address the costs and benefits of SAMDAs, and the bases for not incorporating into the design of the manufactured reactor any SAMDAs identified during the applicant's review. Section 51.54(b) reflects the narrower scope of a environmental report submitted in connection with a proposed amendment to a manufacturing license, by providing that the report need only address whether the design change which is subject of a proposed amendment either renders a SAMDA previously identified and rejected to become cost beneficial, or results in the identification of new SAMDAs that may be reasonably incorporated into the design of the manufactured reactors.

As discussed earlier, the environmental impacts of manufacturing a reactor under a manufacturing license are not considered by the NRC, and § 51.54 indicates that the

environmental report need not include a discussion of the environmental impacts of manufacturing a reactor.

Section 51.55, *Environmental report—standard design certification.*

The provisions in current § 51.55 would be transferred to a new § 51.58 (discussed in § 51.58), and this section would be revised to address the contents of environmental reports for design certifications under subpart B of part 52. The structure of proposed § 51.55 is similar to that of § 51.54, reflecting the fact that the environmental review for either manufacturing licenses or design certifications is limited to SAMDAs. Section 51.55(a) provides that the environmental report for the design certification must address the costs and benefits of SAMDA, and the bases for not incorporating into the design certification any SAMDAs identified during the applicant's review. Section 51.55(b) provides that the environmental report submitted in support of a request to amend a design certification, need only address whether the design change which is the subject of a proposed amendment either renders a SAMDA previously identified and rejected to become cost beneficial, or results in the identification of new SAMDAs that may be reasonably incorporated into the design certification.

Section 51.58, *Environmental report—number of copies; distribution.*

The matters previously addressed in § 51.55 would be addressed in a proposed new § 51.58. Section 51.58(a) would add conforming references for early site permits and combined licenses. Section 51.58(b) would make a conforming reference to subpart F of part 52.

Section 51.71, *Draft environmental impact statement—contents.*

Section 51.71(d) and its associated Footnote 3 would be revised to include a separate discussion with specific requirements for the content of draft environmental impact statements at the early site permit and combined license stages.

Section 51.75, *Draft environmental impact statement—construction permit, early site permit, or combined license.*

Sections 51.75(b) and (c) and a new Footnote 5 would be added to include separate requirements for the preparation of draft EISs at the early site permit and combined license stages. Section 51.75(c) would be organized into separate subparagraphs, which would address the contents of the combined license environmental impact statement if the combined license application references an early site permit or standard design certification or both, or proposes to use a manufactured reactor. For example, § 51.75(c)(3) would provide that the combined license EIS will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

Section 51.95, *Postconstruction environmental impact statements.*

Section 51.95(a) would be revised to indicate that documents that may be referenced in a supplement to a final environmental impact statement include documents prepared in connection with an early site permit or combined license. In addition, § 51.95(c) would be revised to correct the address for the NRC Public Document Room. Section 51.95 would be revised to indicate that the NRC will prepare a supplemental environmental impact statement in connection with the amendment of a combined license authorizing decommissioning activities or with the issuance, amendment, or renewal of a license to store spent fuel at a nuclear power

reactor after expiration of the combined license, and that the supplement may incorporate by reference any information contained in the final environmental impact statement for the combined license or in the records of decision prepared in accordance with an early site permit or combined license. Finally, § 51.95(d) would be revised to indicate that, unless otherwise required by the Commission, the provisions of § 51.23(b), a supplemental environmental impact statement for the post combined license stage will address the environmental impacts of spent fuel storage only for the term of the license, amendment, or renewal applied for.

Section 51.105, Public hearings in proceedings for issuance of construction permits or early site permits.

The section heading and § 51.105(a) would be revised to indicate that the requirements for presiding officers in public hearings on construction permits also apply to public hearings on early site permits. In addition, § 51.105(b) would be added to indicate that the presiding officer in an early site permit hearing shall not admit contentions concerning the benefits assessment (e.g., need for power), or alternative energy sources if the applicant did not address those issues in the early site permit application. In accordance with § 52.17, applicants are not required to address the benefits assessment (e.g., need for power) or alternative energy sources at the early site permit stage.

Section 51.105a, Public hearings in proceedings for issuance of manufacturing licenses.

Section 51.105a would be added to provide requirements for public hearings in proceedings for issuance of manufacturing licenses. Specifically, § 51.105a would establish

that the presiding officer in a proceeding for the issuance of a manufacturing license will (1) determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate to identify all reasonable SAMDAs for the design of the reactor to be manufactured, and evaluate the environmental, technical, economic, and other benefits and costs of each SAMDA; and (2) determine, in a contested proceeding, whether the manufacturing license should be issued as proposed by the NRC staff director (Director of Nuclear Reactor Regulation).

Section 51.107, *Public hearings in proceedings for issuance of combined licenses.*

Section 51.107 would be added to set out the requirements for public hearings in proceedings for issuance of combined licenses. The requirements parallel the associated requirements for public hearings on construction permits and operating licenses, as appropriate, and provide requirements unique to the combined license process that are derived from various provisions in part 52, namely §§ 52.39 and 52.103.

N. Proposed Changes to 10 CFR Part 54.

1. Section 54.1, *Purpose.*

This part applies to renewed operating licenses for nuclear power plants. A conforming change would be made to this section to include renewed combined licenses.

2. Section 54.3, *Definitions.*

The definition for *renewed combined license* would be added to explain the meaning of the new phrase as it is used in this part.

3. Section 54.17, *Filing of application.*

Section 54.17(c) would be revised to add a conforming reference to combined licenses issued under 10 CFR part 52.

4. Section 54.27, *Hearings.*

This section would be revised to include a conforming reference to renewed combined license issued under 10 CFR part 52.

5. Section 54.31, *Issuance of a renewed license.*

Sections 54.31(a), (b), and (c) would be revised to include conforming references to combined licenses in this procedure on issuance of renewed licenses.

6. Section 54.35, *Requirements during term of renewed license.*

This section would be revised to include conforming references to holders of combined licenses and the regulations in part 52 into the requirements for a renewed license.

7. Section 54.37, *Additional records and recordkeeping requirements.*

Section 54.37(a) would be revised to include a conforming reference to a renewed combined license.

O. Proposed Changes to 10 CFR Part 55.

Part 55 establishes the NRC's requirements for licensing of operators of utilization facilities in accordance with the statutory requirements in Section 202 of the ERA. Currently, the provisions in part 55 refer only to utilization facilities licensed under part 50, and therefore, do not address utilization facilities licensed for operation under a combined license issued under subpart C of part 52. Section 202 of the ERA, however, does not limit its mandate to operators of facilities licensed under part 50; the statutory requirement would also appear to apply to operators of facilities licensed under part 52 (i.e., combined licenses under subpart C of part 52).

Accordingly, §§ 55.1 and 55.2 would be revised by adding a reference to part 52. This would clarify that operators of nuclear power reactors licensed under a part 52 combined license or renewed under part 54 must first obtain an operators license under part 55. In addition, the conforming changes would clarify that these operators, as well as holders of combined licenses issued under part 52 or renewed under part 54, are subject to the requirements in part 55 (e.g., Part E of part 55, *Written Examinations and Operating Tests*, set forth requirements which are directed, for the most part, at the holders of operating licenses for utilization facilities).

P. Proposed Changes to 10 CFR Part 72.

1. Section 72.210, *General license issued.*

Part 72 sets forth the requirements for independent spent fuel storage facilities. This section is revised to include a conforming reference to persons authorized to operate nuclear power reactors under 10 CFR part 52 (i.e., a combined license holder).

2. Section 72.218, *Termination of licenses.*

Section 72.218(b) would be revised to include a conforming reference to combined licenses issued under part 52.

Q. Proposed Changes to 10 CFR Part 73.

Part 73 establishes the NRC's requirements for the physical protection of production and utilization facilities licensed by the NRC. It provides requirements for the physical protection of licensed activities, for personnel access authorization, and for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information. Currently, the language of § 73.1, *Purpose and scope*, § 73.2, *Definitions*, § 73.50, *Requirements for physical protection of licensed activities*, § 73.56, *Personnel access authorization requirements for nuclear power plants*, and § 73.57, *Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information by power reactor licensees*, and Appendix C, *Licensee Safeguards Contingency Plans*, do not refer to combined licenses issued under part 52. However, part 73 is currently applicable to combined licenses under the provisions of § 52.83, *Applicability of part 50 provisions*, which states that all provisions of 10 CFR Part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses. Accordingly, § 73.1 would be revised to clarify that the regulations in part 73 apply to persons

who receive combined licenses under part 52, and § 73.2 would be revised to state that terms defined in part 52 have the same meaning when used in part 73. The NRC proposes to address combined licenses in § 73.57 by making the provisions that are required before receiving an operating license under part 50 applicable before the date that the Commission authorizes fuel load and operation under § 52.103 for a combined license. Additional conforming changes to include part 52 licenses are proposed for §§ 73.50 and 73.56, and Appendix C to part 73.

R. Proposed Change to 10 CFR Part 75.

1. Section 75.6, *Maintenance of records and delivery of information, reports, and other communications.*

Part 75 sets forth NRC requirements intended to implement the agreement between the United States and the International Atomic Energy Agency (IAEA) with respect to safeguards of nuclear material. Various provisions throughout part 75 require certain licensees and other individuals and entities regulated by the NRC to submit to the NRC various reports and communications. Section 75.6 specifies the NRC officials to whom these reports and communications are to be sent. However, § 75.6(b) - the provision applying to, *inter alia*, nuclear power plants - refers only to holders of a construction permit or an operating license, and does not include holders of combined licenses. Accordingly, § 75.6(b) would be revised to reference combined licenses. The NRC notes that early site permits and manufacturing licenses need not be referenced, inasmuch as the U.S.-IAEA Safeguards Agreement does not extend to early site permits or manufacturing licenses.

S. Proposed Changes to 10 CFR Part 95.

The following discussion explains the requirements in part 95 generically and covers *Sections 95.5, 95.13, 95.19, 95.20, 95.23, 95.31, 95.33–95.37, 95.39, 95.43, 95.45, 95.49, 95.51, 95.53, 95.57, and 95.59.*

Part 95 sets forth the NRC requirements governing what individuals and entities may be provided access to National Security Information (NSI) and/or Restricted Data (RD) received or developed in connection with activities licensed, certified or regulated by the NRC, and how this information and data is to be protected by these individuals and entities against unauthorized disclosure.

Although requirements for protection of NSI and RD must, by statute, apply to all individuals and entities provided access to such information, various sections in part 95 use slightly different wording to delineate the relevant set of individuals and entities. To ensure consistency, the Commission proposes to revise its regulations to refer to “licensee, certificate holder, or other person,” to describe the individuals and entities subject to the applicable requirements. In adopting this phrase, the NRC intends to ensure that its regulatory requirements for protection of NSI and RD in part 95 extend as broadly as the NRC’s authority provided under applicable law. The term, “licensee,” includes both holders of all NRC licenses, including (but not limited to) combined licenses, as well as holders of permits such as construction permits and early site permits. The term, “certificate holder,” includes (but is not limited to) all certificates of approval that the Commission may issue, such as a certificate of compliance for spent fuel casks under 10 CFR part 72. Finally, the term, “or other person,” is intended to include individuals and entities who are subject to the regulatory authority of the Commission, including applicants for standard design approvals and standard design certifications under part 52. For the same reasons, the Commission proposes to revise § 95.39

to use the phrase, “NRC license, certificate, or standard design approval or standard design certification under part 52.”

T. Proposed Changes to 10 CFR Part 140.

Part 140 addresses the NRC requirements applicable to nuclear reactor licensees with respect to financial protection and indemnity agreements to implement Section 170 of the AEA, commonly referred to as the Price-Anderson Act. In general, the indemnification and financial protection requirements in part 140 become applicable when a holder of a 10 CFR part 50 construction permit who also possesses a materials license under 10 CFR part 70 brings fuel onto the site. However, part 140 currently does not address the indemnification and financial protection requirements of combined license holders. Accordingly, various sections in part 140 are being revised to address combined licenses under part 52.

The NRC does not believe that part 140 must be revised to address any part 52 licensing process other than a combined license. Neither an early site permit nor a manufacturing license authorize the possession or use of nuclear fuel or other nuclear materials, and the NRC would not issue these licenses with a materials license under part 70. The NRC also believes that part 140 need not be revised to address standard design approvals or standard design certifications, because neither of these processes authorize the possession or use of nuclear fuel or other nuclear materials.

U. Proposed Changes to 10 CFR Part 170.

Part 170 sets out the fees charged for licensing services performed by the NRC. Sections 170.2(g) and (k) would be revised to add conforming references to manufacturing

licenses and standard design approvals issued under part 52, remove the reference to Appendix Q that will be returned to part 50, and delete the reference to a manufacturing license issued under part 50 (which is proposed to be removed from part 50 because of its transfer to part 52 in the 1989 rulemaking adopting part 52).

IV. Specific Request for Comments.

In addition to the general invitation to submit comments on the proposed rule, the NRC also requests comments on the following questions:

1. In response to several commenters' concerns about the clarity of the applicability of part 50 provisions to part 52, the Commission has added provisions to part 52 (§§ 52.0 through 52.10a) that are analogues to comparable provisions in part 50. Another possible way of addressing the commenters' concerns would be to transfer all the provisions in part 52 to a new subpart (e.g., subpart M) of part 50, and retain the existing numbering sequence for the current part 52 with the addition of a prefix (e.g., proposed 50.1001 = current 52.1). The Commission is interested in whether stakeholders regard this as a more desirable approach for minimizing the ambiguity of the relationship between part 50 and part 52.

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

submitted by the applicant under § 52.17(b) are acceptable. Section 52.18 does not provide any further explanation of the Commission's criteria for judging the acceptability of major features of emergency plans.

The Commission has concluded, after undergoing the review of the first three early site permit applications, that the concept of Commission review and acceptance of major features of emergency plans may not achieve the same level of finality for emergency preparedness issues at the early site permit stage as that associated with a reasonable assurance finding of complete and integrated plans. Therefore, the NRC requests public comment on whether the early site permit process in proposed Part A should be modified to remove the option for applicants to propose major features of emergency plans in early site permit applications. The NRC believes that, if the option for early site permit applicants to include major features of emergency plans is to be retained, the NRC needs to further define what a major feature is and establish a clearer level of finality associated with the NRC's review and acceptance of major features of emergency plans. If the option to include major features of emergency plans is retained, the NRC would propose to define major features of emergency plans as follows:

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

In addition, the NRC would propose that major features of emergency plans must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in

conformity with the license, the provisions of the Atomic Energy Act, and the NRC's regulations, insofar as they relate to the major features under review.

The NRC believes that, under such a proposal, the level of finality associated with each major feature that the Commission found acceptable would be equivalent, for that individual major feature, to the level of finality associated with a reasonable assurance finding by the NRC for a complete and integrated plan, including ITAAC, at the early site permit stage.

3. As indicated in Section III, *Discussion of Substantive Changes*, the NRC is proposing to remove Appendix Q to part 52 entirely from part 52 and retain it in part 50. Currently, Appendix Q to part 52 provides for NRC staff issuance of a staff site report on site suitability issues with respect to a specific site, for which a person (most likely a potential applicant for a construction permit or combined license) seeks the NRC staff views. The NRC is also interested in stakeholder feedback on whether the early site review process in Appendix Q to part 52 should be removed in its entirety from the NRC's regulations. One possible reason for removing the early site review process in its entirety is that potential nuclear power plant applicants would use the early site permit process in subpart B of part 52, rather than the early site review process as it currently exists in appendix Q to parts 50 and 52. Also, in cases where a combined license applicant was interested in seeking NRC staff review of selected site suitability issues (as appendix Q to part 52 was designed for), the applicant could request a pre-application review of these issues. The use of pre-application reviews for selected issues has been successfully used by applicants for design certification. The NRC is especially interested in the views of potential applicants for nuclear power plant construction permits and combined licenses as to whether there is any value in retaining the early site review process.

4. Under subpart F of part 52 of the proposed rule, the NRC proposes to require approval of, and extend finality to, the final design for a reactor to be manufactured under a manufacturing license. While the NRC will also review the acceptability of the manufacturing

license applicant's organization responsible for design and manufacturing, as well as the QA program for design and manufacturing, the proposed rule does not provide a regulatory structure for further extending the scope of NRC review and issue finality to the manufacturing process itself. The NRC could extend regulatory review approval, and consequently expand issue finality, to the manufacturing itself. There are two models that the Commission could adopt if it were to move in this direction. The first would be an analogue to the subpart C of part 52 combined license process, whereby the NRC would review and approve ITAAC to be included in the manufacturing license. During the manufacturing of each reactor, the NRC would verify at the manufacturing location whether the ITAAC have been conducted and the acceptance criteria met. A NRC finding of successful completion of all the ITAAC would preclude any further inspection of the acceptability of the manufacture of the reactor at the site where the manufactured reactor is to be permanently sited and operated. The NRC's inspections and findings for the combined license or operating license would be limited to whether the reactor had been emplaced in undamaged condition (or damage had been appropriately repaired) and all interface requirements specified in the manufacturing license had been met. The NRC believes that it has authority to issue a manufacturing license under Section 161.h of the AEA.

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

prototype of the reactor had been constructed and tested to demonstrate that all performance requirements (i.e., compliance with NRC requirements and manufacturer's specifications) can be met by the design to be approved for manufacture.

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

5. Currently, part 52 allows an applicant for a construction permit to reference either an early site permit under subpart A of part 52 or a design certification under subpart B of part 52. Specifically, § 52.11 states that Part A of part 52 sets out the requirements and procedures applicable to NRC issuance of early site permits for approval of a site or sites for one or more nuclear power facilities separate from the filing of an application for a construction permit or combined license for such a facility. Similarly, § 52.41 states that subpart B of part 52 sets out the requirements and procedures applicable to NRC issuance of regulations granting standard design certification for nuclear power facilities separate from the filing of an application for a construction permit or combined license for the facility. However, the current regulations in 10 CFR part 50 that address the application for and granting of construction permits do not make any reference to a construction permit applicant's ability to reference either an early site permit or a design certification. Also, the NRC has not developed any guidance on how the construction permit process would incorporate an early site permit or design certification, nor has the nuclear power industry made any proposals for the development of industry guidance on this subject. The NRC has not received any information from potential applicants stating an intention to seek a construction permit for the construction of a future nuclear power plant. In

addition, the NRC recommends that future applicants who want to construct and operate a commercial nuclear power facility use the combined license process in subpart C of part 52. Therefore, the NRC is interested in stakeholder feedback on whether the provisions allowing a construction permit applicant to reference an early site permit or a design certification should be removed in its entirety from 10 CFR part 52.

6. The NRC is considering if § 52.103(a) should be revised to require the combined license holder to notify the NRC of the licensee's scheduled date for loading of fuel into a plant no later than 270 days before the scheduled date, and to advise the NRC every 30 days thereafter if the date has changed and if so, the revised scheduled date for loading of fuel. The initial notification would facilitate timely NRC publication of the notice required under § 52.103(a) and NRC staff scheduling of inspection and audit activities to support NRC staff determinations of the successful completion of ITAAC under § 52.99. The proposed updating would also facilitate NRC staff scheduling of those inspection and audit activities, Commission completion of hearings within the time frame allotted under § 52.103(e), and any Commission determinations on petitions as provided under § 52.103(f). The NRC requests public comment on the benefits and impacts (including information collection and reporting burdens) that would occur if the proposed requirement were adopted.

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

program and its implementation in the combined license application. In this SRM, the Commission stated:

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

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

8. The NRC notes that the backfitting provisions applicable to various part 52 processes are contained in both part 50 and part 52 and, therefore, the proposed language for § 50.109 cross-references to applicable provisions of part 52, which may be confusing. The NRC is considering alternatives to the proposed approach which would remove from § 50.109 the backfitting provisions applicable to the licensing and approval processes in part 52, and place them in part 52. There are two possible approaches for doing so: the first would be for the NRC to establish a general backfitting provision in part 52 applicable exclusively to the licensing and approval processes in part 52. Under this approach, each licensing and approval process in part 52 would be the subject of a backfitting section in a new subpart of part 52 (e.g.,

§ 52.201 for standard design approvals, etc.). The existing backfitting provisions applicable to early site permits and design certification would be transferred to the relevant sections in the new subpart. The second approach would be to ensure that each Part of part 52 contains the backfitting provisions applicable to the licensing or approval process in that subpart. The NRC requests public comment on whether either of these administrative approaches is preferable to the approach in the proposed rule.

V. Availability of Documents.

The NRC is making the documents identified below available to interested persons through one or more of the following methods as indicated.

Public Document Room (PDR). The NRC Public Document Room is located at 11555 Rockville Pike, Rockville, Maryland.

Rulemaking Web site (Web). The NRC’s interactive rulemaking Web site is located at <http://ruleforum.llnl.gov>. These documents may be viewed and downloaded electronically via this Web site.

NRC’s Public Electronic Reading Room (EPDR). The NRC’s electronic public reading room is located at www.nrc.gov/reading-rm.html.

The NRC staff contact. Nanette V. Gilles, Mail Stop O-4D9A, Washington, DC 20555, 301-415-1180.

Document	PDR	Web	EPDR	NRC Staff
Comments received	X	X	X	
Regulatory Analysis	X	X	ML	X
Regulatory History Index for July 2003 proposed rule			ML032810026	

VI. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" which became effective on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC or adequacy category, Health and Safety (H&S). Category A includes program elements that are basic radiation protection standards or related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles and should be essentially identical to those of NRC. Category B includes program elements that have significant direct transboundary implications and should be essentially identical to those of the NRC. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. Compatibility Category D are those program elements that do not meet any of the criteria of Category A, B, or C, and do not need to be adopted by Agreement States. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act, as amended, or provisions of Title 10 of the Code of Federal Regulations and should not be adopted by Agreement States. Category H&S are program elements that are not required for compatibility, but have a particular health and safety role in the regulation of agreement material and the State should adopt the essential objectives of the NRC program elements. The proposed revisions are categorized as follows:

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10 CFR PART 2 - RULES OF PRACTICE FOR DOMESTIC LICENSING AND ISSUANCE OF ORDERS			
2.1	Scope	[D]	Agreement States may adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.4	Definitions		
	Contested proceedings	[D]	Agreement States may adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
	License	[D]	Agreement States adopt similar definition as a part of their regulatory programs. This definition appears in 10 CFR § 20.1003. For purposes of compatibility, Agreement States should use the language of the Part 20 definition, which is assigned a Compatibility Category D.
	Licensee	[D]	Agreement States adopt a similar definition as a part of their regulatory programs. This definition appears in 10 CFR § 20.1003. For purposes of compatibility, Agreement States should use the language of the Part 20 definition, which is assigned a Compatibility Category D.
Subpart A 2.100	Scope of parts	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.101	Filing of application	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.102	Administrative review of application	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction. These similar provisions appears in 10 CFR § 30. For purposes of compatibility, Agreement States should use the language in Part 30, which is assigned a Compatibility Category D.
2.104	Notice of hearing	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.105	Notice of proposed action	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.106	Notice of issuances. Added notice for COL in FR.	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.109	Effect of timely renewal application	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction. These similar provisions appears in 10 CFR § 30. For purposes of compatibility, Agreement States should use the language in Part 30, which is assigned a Compatibility Category D.
2.110	Filing and administrative action on submittal for design review of site suitability	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.111	Prohibition of sex discrimination	[D]	Agreement States may adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
Subpart B 2.200	Scope of subpart	[D]	Agreement States may adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.202	Orders	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
Subpart C 2.390	Public inspections, exemptions, requests for withholding	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
Subpart E 2.500	Scope of subpart	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.501	Notice of hearing on application for license to manufacture nuclear power plants	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.502	Notice of hearing on application for a construction permit for a nuclear power reactor manufactured at the site at which the reactor is to be operated	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
2.503	Finality of decisions on separate issues	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.504	Applicability of other sections	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
Subpart H 2.800	Scope of rulemaking	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.801	Initiation of rulemaking	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.811	Filing of standard design certification application required copies	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.813	Written communications	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.815	Docketing and acceptance review	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
2.817	Withdrawal of application	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
2.819	Denial of application for failure to supply information	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
10 CFR PART 10 - CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION OR AN EMPLOYMENT CLEARANCE			
10.1	Purpose	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
10.2	Scope	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.
10 CFR PART 19 - NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTION AND INVESTIGATIONS			
19.1	Purpose	D	Agreement States may adopt similar provisions consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.
19.2	Scope	D	Agreement States may adopt similar provisions consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.
19.3	Definitions		
	Regulated activities	D	Agreement States may adopt a similar definition consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.
	Regulated entities	D	Agreement States may adopt a similar definition consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
	Worker	C	This provision is currently designated a Compatibility Category C. However, since the proposed revisions address areas of exclusive NRC jurisdiction, Agreement States should not adopt these amendments.
19.11	Posting of notices to workers	C	This provision is currently designated a Compatibility Category C. However, since the proposed revisions address areas of exclusive NRC jurisdiction, Agreement States should not adopt these amendments.
19.14	Presence of representatives of licensees and workers during inspections	C	This provision is currently designated a Compatibility Category C. However, since the proposed revisions address areas of exclusive NRC jurisdiction, Agreement States should not adopt these amendments.
19.20	Employee protection	D	Agreement States may adopt similar provisions consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.
19.31	Application for exemptions	D	Agreement States may adopt similar provisions consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.
19.32	Discrimination prohibited	D	Agreement States may adopt similar provisions consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.
10 CFR PART 20 - STANDARDS OF PROTECTION			
20.1002	Scope	D	Agreement States may adopt similar provisions consistent with their regulatory authority, but should not address areas of exclusive NRC jurisdiction.
20.1401	General provisions and scope	C	This provision is currently designated a Compatibility Category C. However, since the proposed revisions address areas of exclusive NRC jurisdiction, Agreement States should not adopt these amendments.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
20.2203	Reports of exposures, etc., exceeding the limits.	C- paragraphs (a), (b) D- paragraph (d) NRC- paragraph (c)	Portions of this provision is currently designated a Compatibility Category C. However, since the proposed revisions address areas of exclusive NRC jurisdiction, Agreement States should not adopt these amendments.
10 CFR PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE			
21.2	Scope	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.3	Definitions	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
21.5	Communication	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.21	Notification of failure to comply or existence of a defect	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
21.51	Maintenance and inspections of records	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
21.61	Failure to notify	N/A	The provisions in Part 21 are derived from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so. States that have the statutory authority to implement provisions similar to those in Part 21 may adopt similar provisions consistent with their regulatory authority but should not address areas of exclusive NRC jurisdiction.
10 CFR PART 25 - ACCESS AUTHORIZATION			
25.35	Classified visits	NRC	This provision is designated a Compatibility Category NRC because it addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10 CFR PART 26 - FITNESS FOR DUTY PROGRAMS			
26.2	Scope	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
26.10	General performance objectives	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.
10 CFR PART 50	Domestic licensing of production and utilization facilities	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 51	Environmental protection regulation for domestic licensing and related regulatory functions	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 52	Licenses, certifications, and approvals for nuclear power plants	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 54	Requirements for renewal of operating licenses for nuclear power plants	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 55	Operators' licenses	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 72	Licensing requirements for ISFSI, HLW, and greater than class C	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 73	Physical protection of plants and materials	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.

List of Changes 10 CFR Part 52 Proposed Rulemaking

Proposed Sections	Description-New, Changes	Compatibility Designation	Comments Regarding Compatibility Designation
10 CFR PART 75	Safeguards on nuclear material	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 95	Facility security clearance and safeguarding of national security information and restricted data	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR PART 140	Financial protection requirements and indemnity agreements	NRC FOR ALL SECTIONS	These provisions are designated a Compatibility Category NRC because they addresses activities reserved to the Commission.
10 CFR Part 170	Annual fees	[D]	Agreement States adopt similar provisions as a part of their regulatory programs through a mechanism that is appropriate under the State's laws, but should not address areas of exclusive NRC jurisdiction.

VII. Plain Language.

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). In complying with this directive, the NRC made editorial changes to improve the organization and readability of the existing language of the paragraphs being revised. These types of changes are not discussed further in this document. The NRC requests comments on the proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be submitted using one of the methods detailed under the ADDRESSES heading of the preamble to this proposed rule.

VIII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this rule, the NRC is proposing to revise the procedural requirements for early site permits, standard design approvals, standard design certifications, combined licenses, and manufacturing licenses to make certain corrections and changes based on the experience of the previous design certification reviews and on discussions with stakeholders on these licensing processes. This rulemaking does not establish standards or substantive the requirements with which all applicants and licensees must comply. In addition, this rule would amend certain portions of the three design certification regulations in 10 CFR part 52, appendices A, B, and C (for U.S. ABWR, System 80+, and AP600 designs, respectively). Design certifications are not generic rulemakings in the sense

that design certifications do not establish standards or requirements with which all applicants and licensees must comply. Rather, design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certification rulemakings are initiated by an applicant for a design certification, rather than the NRC. For these reasons, the Commission concludes that this action would not constitute the establishment of a standard that contains generally applicable requirements.

IX. Environmental Impact - Categorical Exclusion.

The NRC has determined that the changes made in this rule fall within the types of actions described in categorical exclusions 10 CFR 51.22(c)(1), (c)(2), and (c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.¹⁰

X. Paperwork Reduction Act Statement.

This proposed rule amends information collection requirements contained in 10 CFR part 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). These information collection requirements have been submitted to the Office of

¹⁰When 10 CFR part 52 was issued in 1989, the NRC determined that the regulation met the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(3). As stated in the *Federal Register* notice for the final rule (54 FR 15384; April 18, 1989), "It makes no substantive difference for the purpose of the categorical exclusion that the amendments are in a new 10 CFR part 52 rather than in 10 CFR part 50. The amendments are, in fact, amendments to the 10 CFR part 50 procedures and could have been placed in that part." The categorical exclusion for the current proposed change to 10 CFR part 52 is consistent with the original categorical exclusion determination. To ensure that future changes in part 52 are categorically excluded, the proposed rule contains an appropriate change to § 51.22(c)(3).

Management and Budget for review and approval. The proposed changes to 10 CFR parts 2, 19, 20, 21, 25, 26, 50, 51, 54, 55, 72, 73, 75, 95, 140, and 170 do not contain new or amended information collection requirements. Existing requirements were approved by the Office of Management and Budget, approval number(s) 3150-0014, 3150-0035, 3150-0011, 3150-0021, 3150-0132, 3150-0039, and 3150-0002.

The burden to the public for the information collections in 10 CFR part 52 is estimated to average 3,429 hours per response. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden, to the Records Management Branch (T5-F52), U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, or by Internet electronic mail to INFCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0151, 3150-0011, and 3150-0039), Office of Management and Budget, Washington, D.C. 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XI. Regulatory Analysis.

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis can be viewed in NRC's ADAMS system, Accession Number ML052840320. The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

XII. Regulatory Flexibility Certification.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing of nuclear power plants. The companies that will apply for an approval, certification, permit, site report, or license in accordance with the regulations affected by this proposed rule do not fall within the

scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XIII. Backfit Analysis.

The NRC has determined that the backfit rule does not apply to this proposed rule and, therefore, a backfit analysis is not required, because the proposed rule does not contain any provisions that would impose backfitting as defined in the backfit rule, 10 CFR 50.109.

There are no current holders of early site permits, combined licenses, or manufacturing licenses that would be protected by the backfitting restrictions in § 50.109. To the extent that the proposed rule would revise the requirements for future early site permits, standard design certifications, combined licenses, standard design approvals and manufacturing licenses for nuclear power plants, these revisions would not constitute backfits because they are prospective in nature and the backfit rule was not intended to apply to every NRC action which substantially changes the expectations of future applicants.

Other provisions in the proposed rule would apply to currently-approved standard design approvals and certifications, but these would not constitute backfitting because they are either corrections, administrative changes, or provide additional flexibility to applicants or licensees who might reference the design approvals or certifications, and thus constitute a voluntary alternative or relaxation.

Finally, some of the provisions in the proposed rule represent conforming changes throughout 10 CFR which are being made to reflect Commission adoption of design approvals and design certification processes which should have been made at the time the Commission first adopted these processes by rulemaking. While these conforming changes may, in some cases, affect the way in which a current design certification or design approval may be

referenced, they do not directly affect the design approval or design certification itself. Accordingly, the Commission believes that these conforming changes with respect to design approvals and design certifications do not raise new backfitting considerations that must be addressed in this rulemaking.

List of Subject Index Terms

10 CFR Part 1

Organization and functions (Government Agencies).

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 10

Administrative practice and procedure, Classified information, Government employees, Security measures.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and record keeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and record keeping requirements.

10 CFR Part 25

Classified information, Criminal penalties, Investigations, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 26

Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power reactors, Protection of information, Reporting and recordkeeping requirements.

10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Emergency Planning, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and record keeping requirements.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and record keeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR Part 54

Administrative practice and procedure, Age-related degradation, Backfitting, Classified information, Criminal penalties, Environmental protection, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 55

Criminal penalties, Manpower training programs, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and record keeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and record keeping requirements, Security measures.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and record keeping requirements, Security measures.

10 CFR Part 95

Classified information, Criminal penalties, Reporting and recordkeeping requirements Security measures.

10 CFR Part 140

Criminal penalties, Extraordinary nuclear occurrence, Insurance, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

For the reasons set forth in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C.

553, the NRC is proposing to adopt the following amendments to 10 CFR parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52, 54, 55, 72, 73, 75, 95, 140, and 170.

PART 1 — STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. The authority citation for Part 1 continues to read as follows:

AUTHORITY: Secs. 23, 161, 68 Stat. 925, 948, as amended (42 U.S.C. 2033, 2201); sec. 29, Pub. L. 85-256, 71 Stat. 579, Pub. L. 95-209, 91 Stat. 1483 (42 U.S.C. 2039); sec. 191, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); secs. 201, 203, 204, 205, 209, 88 Stat.1242, 1244, 1245, 1246, 1248, as amended (42 U.S.C. 5841, 5843, 5844, 5845, 5849); 5 U.S.C. 552, 553; Reorganization Plan No. 1 of 1980, 45 FR 40561, June 16, 1980.

2. In § 1.43, paragraph (a)(2) is revised to read as follows:

§ 1.43 Office of Nuclear Reactor Regulation.

* * * * *

(a) * * *

(2) Receipt, possession, and ownership of source, byproduct, and special nuclear material used or produced at facilities licensed under 10 CFR parts 50, 52, and 54;

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**PART 2 — RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND
ISSUANCE OF ORDERS**

3. The authority citation for Part 2 continues to read as follows:

AUTHORITY: Secs.161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552; sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97-425, 96 Stat. 2213, as amended (42 U.S.C. 10143(o)), sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 104, 105, 163, 183i, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Sections 2.105 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200--2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948-951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Section 2.205(j) also issued under Pub. L. 101-410, 104 Stat. 90, as amended by Section 3100(s), Pub. L. 104-134, 110 Stat. 1321-373 (28 U.S.C. 2461 note). Subpart C also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332). Section 2.700a also issued under 5 U.S.C. 554. Sections 2.343, 2.346, 2.754, 2.712 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133), and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553, and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart M also issued under sec. 184 (42 U.S.C. 2234) and sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart N also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91-550, 84 Stat. 1473 (42 U.S.C. 2135).

4. In § 2.1, paragraphs (c) and (d) are revised and a new paragraph (e) is added to read as follows:

§ 2.1 Scope.

* * * *

- (c) Imposing civil penalties under section 234 of the Act;
- (d) Rulemaking under the Act and the Administrative Procedures Act; and
- (e) Standard design approvals under part 52 of this chapter.

5. In § 2.4, the definitions of *contested proceeding*, *license* and *licensee* are revised to read as follows:

§ 2.4 Definitions.

* * * *

Contested proceeding means –

- (1) A proceeding in which there is a controversy between the NRC staff and the applicant for a license or permit concerning the issuance of the license or permit or any of the terms or conditions thereof;
- (2) A proceeding in which the NRC is imposing a civil penalty or other enforcement action, and the subject of the civil penalty or enforcement action; and
- (3) A proceeding in which a petition for leave to intervene in opposition to an application for a license or permit has been granted or is pending before the Commission.

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License means a license, including an early site permit, construction permit, operating license, combined license, manufacturing license, or renewed license issued by the Commission.

Licensee means a person who is authorized to conduct activities under a license.

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6. The heading of Subpart A is revised to read as follows:

**Subpart A - Procedure for Issuance, Amendment, Transfer, or Renewal of a License, and
Standard Design Approval**

7. Section 2.100 is revised to read as follows:

§ 2.100 Scope of subpart.

This subpart prescribes the procedure for issuance of a license; amendment of a license at the request of the licensee; transfer and renewal of a license; and issuance of a standard design approval under subpart E of part 52 of this chapter.

8. In § 2.101, paragraphs (a)(1), (a)(2), the introductory text of paragraph (a)(3), paragraphs (a)(3)(ii), and paragraph (a)(4) are revised to read as follows:

§ 2.101 Filing of application.

(a)(1) An application for a permit, license, a license transfer, a license amendment, a license renewal, and standard design approval, shall be filed with the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as prescribed by the applicable provisions of this chapter. A prospective applicant may confer informally with the NRC staff before filing an application.

(2) Each application for a license for a facility or for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee will be assigned a docket number. However, to allow a determination as to whether an application for a construction permit, operating license, early site permit, standard design approval,

combined license, or manufacturing license for a production or utilization facility is complete and acceptable for docketing, it will be initially treated as a tendered application. A copy of the tendered application will be available for public inspection at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room. Generally, the determination on acceptability for docketing will be made within a period of 30 days. However, in selected applications, the Commission may decide to determine acceptability based on the technical adequacy of the application as well as its completeness. In these cases, the Commission, under § 2.104(a), will direct that the notice of hearing be issued as soon as practicable after the application has been tendered, and the determination of acceptability will be made generally within a period of 60 days. For docketing and other requirements for applications under part 61 of this chapter, see paragraph (g) of this section.

(3) If the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, determines that a tendered application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license for a production or utilization facility, and/or any environmental report required under subpart A of part 51 of this chapter, or part thereof as provided in paragraphs (a)(5) or (a-1) of this section are complete and acceptable for docketing, a docket number will be assigned to the application or part thereof, and the applicant will be notified of the determination. With respect to the tendered application and/or environmental report or part thereof that is acceptable for docketing, the applicant will be requested to:

* * * *

(ii) Serve a copy on the chief executive of the municipality in which the facility or site which is the subject of an early site permit is to be located or, if the facility or site which is the subject of an early site permit is not to be located within a municipality, on the chief executive of the county, and serve a notice of availability of the application or environmental report on the

chief executives of the municipalities or counties which have been identified in the application or environmental report as the location of all or part of the alternative sites, containing the following information, as applicable: Docket number of the application, a brief description of the proposed site and facility; the location of the site and facility as primarily proposed and alternatively listed; the name, address, telephone number, and email address (if available) of the applicant's representative who may be contacted for further information; notification that a draft environmental impact statement will be issued by the Commission and will be made available upon request to the Commission; and notification that if a request is received from the appropriate chief executive, the applicant will transmit a copy of the application and environmental report, and any changes to these documents which affect the alternative site location, to the executive who makes the request. In complying with the requirements of this paragraph, the applicant should not make public distribution of those parts of the application subject to § 2.390(d). The applicant shall submit to the Director of Nuclear Reactor Regulation an affidavit that service of the notice of availability of the application or environmental report has been completed along with a list of names and addresses of those executives upon whom the notice was served; and

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(4) The tendered application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license will be formally docketed upon receipt by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, of the required additional copies. Distribution of the additional copies shall be deemed to be complete as of the time the copies are deposited in the mail or with a carrier prepaid for delivery to the designated addresses. The date of docketing shall be the date when the required copies are received by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate.

Within 10 days after docketing, the applicant shall submit to the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, an affidavit that distribution of the additional copies to Federal, State, and local officials has been completed in accordance with the requirements of this chapter and written instructions furnished to the applicant by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate. Amendments to the application and environmental report shall be filed and distributed and an affidavit shall be furnished to the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, in the same manner as for the initial application and environmental report. If it is determined that all or any part of the tendered application and/or environmental report is incomplete and therefore not acceptable for processing, the applicant will be informed of this determination, and the respects in which the document is deficient.

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9. In § 2.102, paragraph (a) is revised to read as follows:

§ 2.102 Administrative review of application.

(a) During review of an application by the NRC staff, an applicant may be required to supply additional information. The staff may request any one party to the proceeding to confer with the staff informally. In the case of a docketed application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license of this chapter, the staff shall establish a schedule for its review of the application, specifying the key intermediate steps from the time of docketing until the completion of its review.

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10. In § 2.104, the introductory text of paragraph (a) is revised, current paragraphs (d) and (e) are redesignated as paragraphs (l) and (m) and revised, respectively, new paragraphs (d), (e), and (f) are added, and paragraphs (h) through (k) are added and reserved, and footnote 1 is revised to read as follows:

§ 2.104 Notice of hearing.

(a) In the case of an application on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest, the Secretary will issue a notice of hearing to be published in the *Federal Register* as required by law at least 15 days, and in the case of an application concerning a construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter or a testing facility, at least 30 days, before the date set for hearing in the notice.¹¹ In addition, in the case of an application for an early site permit, construction permit or combined license for a facility of the type described in § 50.22 of this chapter, or a testing facility, the notice (other than a notice under paragraph (d) of this section) shall be issued as soon as practicable after the application has been docketed; provided, that if the Commission, under § 2.101(a)(2), decides to determine the acceptability of the application based on its technical adequacy as well as completeness, the notice shall be issued as soon as practicable after the application has been tendered. The notice will state:

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¹¹If the notice of hearing concerning an application for a construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter or a testing facility does not specify the time and place of initial hearing, a subsequent notice will be published in the *Federal Register* which will provide at least 30 days notice of the time and place of that hearing. After this notice is given the presiding officer may reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing at least 30 days notice.

(d) In the case of an application for an early site permit under subpart A of part 52, the notice will, except as the Commission determines otherwise, state, in implementation of paragraph (a)(3) of this section:

(1) If the proceeding is a contested proceeding, the presiding officer will consider the following issues:

(i) Whether applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Whether any required notifications to other agencies or bodies have been duly made;

(iii) If the applicant requests authorization to perform the activities under § 52.17(c), whether there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type described in the application from the standpoint of radiological health and safety considerations under the Act and regulations issued by the Commission.

(iv) Whether there is reasonable assurance that the site is in conformity with the provisions of the Act, and the Commission's regulations;

(v) Whether the applicant is technically qualified to engage in any activities authorized;

(vi) Whether the proposed inspections, tests, analyses and acceptance criteria, including any on emergency planning, are necessary and sufficient within the scope of the early site permit to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(vii) Whether issuance of the early site permit will be inimical to the common defense and security or to the health and safety of the public; and

(viii) Whether, in accordance with the requirements of subpart A of part 52 of this chapter and subpart A of part 51 of this chapter, the early site permit should be issued as proposed.

(2) If the proceeding is not a contested proceeding, the presiding officer will determine, without conducting a *de novo* evaluation of the application, whether:

(i) The application and the record of the proceeding contain sufficient information, and the review of the application by the NRC staff has been adequate to support affirmative findings on paragraphs (d)(1)(i) through (v), and (vii) of this section, and a negative finding on paragraph (d)(1)(vi) of this section; and

(ii) The review conducted under part 51 of this chapter under the National Environmental Policy Act (NEPA) has been adequate.

(3) Regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with subpart A of part 51 of this chapter:

(i) Determine whether the requirements of section 102(2) (A), (C), and (E) of the NEPA and subpart A of part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determine the appropriate action to be taken; and

(iii) If the applicant requests authorization to perform the activities under § 52.17(c), whether there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type described in the application from the standpoint of radiological health and safety considerations under the Act and regulations issued by the Commission.

(iv) Determine whether the combined license should be issued, denied or appropriately conditioned to protect environmental values.

(e) In the case of an application for a combined license under subpart C of part 52 of this chapter, the notice will, except as the Commission determines otherwise, state, in implementation of paragraph (a)(3) of this section:

(1) If the proceeding is a contested proceeding, the presiding officer will consider the following issues:

(i) Whether applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Whether any required notifications to other agencies or bodies have been duly made;

(iii) Whether there is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations.

(iv) Whether the applicant is technically and financially qualified to engage in the activities authorized;

(v) Whether issuance of the license will not be inimical to the common defense and security or to the health and safety of the public.

(vi) Whether the proposed inspections, tests, analyses, and acceptance criteria, including those applicable to emergency planning, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(vii) Whether any inspections, tests, or analyses have been successfully completed and the acceptance criteria in a referenced early site permit, standard design certification or for a manufactured reactor have been met, but only to the extent that the combined license application represents that those inspections, tests and analyses have been successfully completed and the acceptance criteria have been met;

(viii) Whether the issuance of the combined license will be inimical to the common defense and security or to the health and safety of the public; and

(ix) Whether, in accordance with the requirements of subpart C of part 52 of this chapter and subpart A of part 51 of this chapter, the combined license should be issued as proposed.

(2) If the proceeding is not a contested proceeding, the presiding officer will determine, without conducting a *de novo* evaluation of the application, if:

(i) The application and the record of the proceeding contain sufficient information, and the review of the application by the NRC staff has been adequate to support affirmative findings on paragraphs (e)(1)(i) through (vii), and (ix) of this section, and a negative finding on paragraph (e)(1)(viii) of this section; and

(ii) The review conducted under part 51 of this chapter under NEPA has been adequate.

(3) Regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with subpart A of part 51 of this chapter:

(i) Determine whether the requirements of section 102(2) (A), (C), and (E) of the NEPA and subpart A of part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determine the appropriate action to be taken; and

(iii) Determine whether the combined license should be issued, denied or appropriately conditioned to protect environmental values.

(f) In the case of an application for a manufacturing license under subpart F of part 52 of this chapter, the issues stated in the notice of hearing under paragraph (a)(3) of this section will not involve consideration of the particular sites at which any of the nuclear power reactors to be manufactured will be located and operated. Except as the Commission determines otherwise, the notice of hearing will state:

(1) If the proceeding is a contested proceeding, the presiding officer will consider the following issues:

(i) Whether applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Whether there is reasonable assurance that the reactor(s) will be manufactured, and can be transported, incorporated into a nuclear power plant, and operated in conformity with the manufacturing license, the provisions of the Act, and the Commission's regulations;

(iii) Whether the proposed reactor(s) to be manufactured can be incorporated into a nuclear power plant at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactor(s) without undue risk to the health and safety of the public;

(iv) Whether the applicant is technically qualified to design and manufacture the proposed nuclear power reactor(s);

(v) Whether the proposed inspections, tests, analyses, and acceptance criteria are necessary and sufficient, within the scope of the manufacturing license, to provide reasonable assurance that the reactor has been manufactured and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(vi) Whether the issuance of a license for manufacture of the reactor(s) will be inimical to the common defense and security or to the health and safety of the public; and

(vii) Whether, in accordance with the requirements of subpart F of part 52 and subpart A of part 51, the license should be issued as proposed.

(2) If the proceeding is not a contested proceeding, the presiding officer will determine, without conducting a *de novo* evaluation of the application, whether:

(i) The application and the record of the proceeding contain sufficient information, and the review of the application by the NRC staff has been adequate to support affirmative findings

on paragraphs (f)(1)(i) through (v), and (vii) of this section proposed to be made and a negative finding on paragraph (f)(1)(vi) of this section; and

(ii) The review conducted under part 51 of this chapter under NEPA has been adequate.

(3) Regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with subpart A of part 51:

(i) Determine whether the requirements of section 102(2) (A), (C), and (E) of the National Environmental Policy Act and subpart A of part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determine the appropriate action to be taken; and

(iii) Determine whether the manufacturing license should be issued, denied or appropriately conditioned to protect environmental values.

(4) The place of hearing on an application for a manufacturing license will be Bethesda, Maryland, or such other location as the Commission deems appropriate.

(g)-(k) **RESERVED**

(l) In an application for a construction permit or an operating license for a facility on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest to consider the antitrust aspects of the application, the notice of hearing will, unless the Commission determines otherwise, state:

(1) A time of the hearing, which will be as soon as practicable after the receipt of the Attorney General's advice and compliance with sections 105 and 189a of the Act and this part;

(2) The presiding officer for the hearing who shall be either an administrative law judge or an atomic safety and licensing board established by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel;

(3) That the presiding officer will consider and decide whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws described in Section 105a of the Act; and

(4) That matters of radiological health and safety and common defense and security, and matters raised under NEPA, will be considered at another hearing if otherwise required or ordered to be held, for which a notice will be published under paragraphs (a) and (b) of this section, unless otherwise authorized by the Commission.

(m)(1) The Secretary will transmit a notice of hearing on an application for a license for a production or utilization facility including an early site permit, combined license (but not for a manufacturing license), for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, for a license under part 61 of this chapter, for a construction authorization for a HLW repository at a geologic repository operations area under parts 60 or 63 of this chapter, for a license to receive and possess high-level radioactive waste at a geologic repository operations area under parts 60 or 63 of this chapter, and for a license under part 72 of this chapter to acquire, receive or possess spent fuel for the purpose of storage in an independent spent fuel storage installation (ISFSI) to the governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be located or conducted within an Indian reservation).

(2) The Secretary will transmit a notice of opportunity for hearing under § 52.103 of this chapter on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the combined license, except for those ITAAC that the Commission found were met under § 52.97, to the governor or other appropriate official of the State and to the chief

executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be located or conducted within an Indian reservation).

(3) The Secretary will transmit a notice of hearing on an application for a license under part 72 of this chapter to acquire, receive or possess spent fuel, high-level radioactive waste or radioactive material associated with high-level radioactive waste for the purpose of storage in a monitored retrievable storage installation (MRS) to the same persons who received the notice of docketing under § 72.16(e) of this chapter.

11. In § 2.105, the introductory text of paragraphs (a) and (a)(4) are revised, and paragraphs (a)(12) and (b)(3) are added to read as follows:

§ 2.105 Notice of proposed action.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, before acting thereon, publish in the *Federal Register*, as applicable, a document under § 52.103(a) of this chapter with respect to a finding that inspections, tests, analyses, and acceptance criteria for a combined license under subpart C of part 52 have been met, or a notice of proposed action with respect to an application for:

* * * *

(4) An amendment to an operating license, combined license or manufacturing license for a facility licensed under §§ 50.21(b) or 50.22 of this chapter, or for a testing facility, as follows:

* * * *

(12) An amendment to an early site permit issued under subpart B of part 52 of this chapter, as follows:

(i) If the early site permit does not provide authority to conduct the activities allowed under § 50.10(e)(1) of this chapter, the amendment will involve no significant hazards consideration, and though the NRC will provide notice of opportunity for a hearing under this section, it may make the amendment immediately effective and grant a hearing thereafter; and

(ii) If the early site permit provides authority to conduct the activities allowed under § 50.10(e)(1) and the Commission determines under §§ 50.58 and 50.91 of this chapter that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing under § 2.106 of this chapter (if a hearing is requested, which will be held after issuance of the amendment).

(b)* * *

(3) For a notice of intended operation under § 52.103(a) of this chapter, the following information:

(i) The identification of the NRC action as making the finding required under § 52.103(g) of this chapter;

(ii) The manner in which copies of the safety analysis may be obtained and examined;

(iii) A finding that the application for the license or amendment complies with the requirements of the Act and this chapter, including successful completion of all inspections, tests, analyses, and acceptance criteria; and

(iv) Any conditions, limitations or restrictions to be placed on the license in connection with the finding under § 52.103(g) of this chapter, and the expiration date or circumstances (if any) under which the conditions, limitations or restrictions will no longer apply.

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12. In § 2.106, paragraphs (a) and (b) are revised to read as follows:

§ 2.106 Notice of issuance.

(a) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the State and local officials specified in § 2.104(e) and publish a document in the *Federal Register* announcing the issuance of:

(1) A license or an amendment of a license for which a notice of proposed action has been previously published;

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter, or a testing facility, whether or not a notice of proposed action has been previously published; and

(3) The finding under § 52.103(g) of this chapter.

(b) The notice of issuance will set forth:

(1) In the case of a license or amendment:

(i) The nature of the license or amendment;

(ii) The manner in which copies of the safety analysis, if any, may be obtained and examined; and

(iii) A finding that the application for the license or amendment complies with the requirements of the Act and this chapter.

(2) In the case of a finding under § 52.103(g) of this chapter:

(i) The manner in which copies of the safety analysis, if any, may be obtained and examined; and

(ii) A finding that the prescribed inspections, tests, and analyses have been performed, the prescribed acceptance criteria have been met, and that the license complies with the requirements of the Act and this chapter.

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13. Section 2.109 is revised to read as follows:

§ 2.109 Effect of timely renewal application.

(a) Except for the renewal of an operating license for a nuclear power plant under 10 CFR 50.21(b) or 50.22, an early site permit under subpart A of part 52 of this chapter, a manufacturing license under subpart F of part 52 of this chapter, or a combined license under subpart C of part 52 of this chapter, if at least 30 days before the expiration of an existing license authorizing any activity of a continuing nature, the licensee files an application for a renewal or for a new license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

(b) If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 50.22 files a sufficient application for renewal of either an operating license or a combined license at least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

(c) If the holder of an early site permit licensed under subpart A of part 52 of this chapter files a sufficient application for renewal under § 52.29 of this chapter at least 12 months before the expiration of the existing early site permit, the existing permit will not be deemed to have expired until the application has been finally determined.

(d) If the licensee of a manufacturing license under subpart F of part 52 of this chapter files a sufficient application for renewal under § 52.177 of this chapter at least 12 months before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

14. Section 2.110 is revised to read as follows:

§ 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

(a)(1) A submittal for a standard design approval under subpart E of part 52 of this chapter shall be subject to §§ 2.101(a) and 2.390 to the same extent as if it were an application for a permit or license.

(2) Except as specifically provided otherwise by the provisions of appendix Q to part 50 of this chapter, a submittal for early review of site suitability issues under appendix Q to part 50 of this chapter shall be subject to §§ 2.101(a)(2) through (4) to the same extent as if it were an application for a permit or license.

(b) Upon initiation of review by the NRC staff of a submittal for an early review of site suitability issues under appendix Q of part 50 of this chapter, or for a standard design approval under subpart E of part 52 of this chapter, the Director of Nuclear Reactor Regulation shall publish in the *Federal Register* a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or other time as may be specified, for consideration by the NRC staff and ACRS in their review.

(c)(1) Upon completion of review by the NRC staff and the ACRS of a submittal for a standard design approval, the Director of the Office of Nuclear Reactor Regulation shall publish in the *Federal Register* a determination as to whether or not the design is acceptable, subject to terms and conditions as may be appropriate, and shall make available at the NRC Web site, <http://www.nrc.gov>, a report that analyzes the design.

(2) Upon completion of review by the NRC staff and, if appropriate by the ACRS, of a submittal for early review of site suitability issues, the NRC staff shall prepare a staff site report which shall identify the location of the site, state the site suitability issues reviewed, explain the nature and scope of the review, state the conclusions of the staff regarding the issues reviewed and state the reasons for those conclusions. Upon issuance of an NRC staff site report, the NRC staff shall publish a notice of the availability of the report in the *Federal Register* and shall make the report available at the NRC Web site, <http://www.nrc.gov>. The NRC staff shall also

send a copy of the report to the Governor or other appropriate official of the State in which the site is located, and to the chief executive of the municipality in which the site is located or, if the site is not located in a municipality, to the chief executive of the county.

15. Section 2.111 is revised to read as follows:

§ 2.111 Prohibition of sex discrimination.

No person shall on the grounds of sex be excluded from participation in, be denied a license, standard design approval, or petition for rulemaking (including a design certification), be denied the benefits of, or be subjected to discrimination under any program or activity carried on or receiving Federal assistance under the Act or the Energy Reorganization Act of 1974.

16. In § 2.202, paragraph (e) is revised to read as follows:

§ 2.202 Orders.

* * * *

(e)(1) If the order involves the modification of a part 50 license and is a backfit, the requirements of § 50.109 of this chapter shall be followed, unless the licensee has consented to the action required.

(2) If the order involves the modification of combined license under subpart C of part 52 of this chapter, the requirements of § 52.98 of this chapter shall be followed unless the licensee has consented to the action required.

(3) If the order involves a change to an early site permit under subpart A of part 52 of this chapter, the requirements of § 52.39 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

(4) If the order involves a change to a standard design certification rule referenced by that plant's application, the requirements, if any, in the referenced design certification rule with

respect to changes must be followed, or, in the absence of these requirements, the requirements of § 52.63 of this chapter must be followed, unless the applicant or licensee has consented to follow the action required.

(5) If the order involves a change to a standard design approval referenced by that plant's application, the requirements of § 52.145 of this chapter must be followed unless the applicant or licensee has consented to follow the action required.

(6) If the order involves a modification of a manufacturing license under subpart F of part 52, the requirements of § 52.171 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

17. In § 2.390, the introductory text of paragraph (a) is revised to read as follows:

§ 2.390 Public inspections, exemptions, requests for withholding.

(a) Subject to the provisions of paragraphs (b), (d), (e), and (f) of this section, final NRC records and documents, including but not limited to correspondence to and from the NRC regarding the issuance, denial, amendment, transfer, renewal, modification, suspension, revocation, or violation of a license, permit, order, or standard design approval, or regarding a rulemaking proceeding subject to this part shall not, in the absence of an NRC determination of a compelling reason for nondisclosure after a balancing of the interests of the person or agency urging nondisclosure and the public interest in disclosure, be exempt from disclosure and will be made available for inspection and copying at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, except for matters that are:

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18. Section 2.500 is revised to read as follows:

§ 2.500 Scope of subpart.

This subpart prescribes procedures applicable to licensing proceedings which involve the consideration in separate hearings of an application for a license to manufacture nuclear power reactors under subpart F of part 52 of this chapter.

19. In § 2.501, the section heading, the introductory language of paragraph (a), and paragraph (b) are revised to read as follows:

§ 2.501 Notice of hearing on application under subpart F of part 52 for a license to manufacture nuclear power reactors.

(a) In the case of an application under subpart F of part 52 of this chapter for a license to manufacture nuclear power reactors of the type described in § 50.22 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the *Federal Register* at least 30 days before the date set for hearing in the notice.¹¹ The notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

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(b) The notice of hearing shall comply with the requirements of § 2.104(f) of this chapter.

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20. Remove and reserve § 2.502.

§ 2.502 [REMOVED AND RESERVED]

¹¹The thirty (30) day requirement of this paragraph is not applicable to a notice of the time and place of hearing published by the presiding officer after the notice of hearing described in this section has been published.

21. Remove and reserve § 2.503.

§ 2.503 [REMOVED AND RESERVED]

22. Remove and reserve § 2.504.

§ 2.504 [REMOVED AND RESERVED]

23. In § 2.800 the section heading and text are revised to read as follows:

§ 2.800 Scope and applicability.

(a) This subpart governs the issuance, amendment, and repeal of regulations in which participation by interested persons is prescribed under section 553 of title 5 of the U.S. Code.

(b) The procedures in §§ 2.804 through 2.810 apply to all rulemakings.

(c) The procedures in §§ 2.802 through 2.803 apply to all petitions for rulemaking except for initial applications for standard design certification rulemaking under subpart B of part 52 of this chapter, and subsequent petitions for amendment of an existing design certification rule filed by the original applicant for the design certification rule.

(d) The procedures in §§ 2.811 through 2.819, as supplemented by the provisions of subpart B of part 52, apply to standard design certification rulemaking.

24. Section 2.801 is revised to read as follows:

§ 2.801 Initiation of rulemaking.

Rulemaking may be initiated by the Commission at its own instance, on the recommendation of another agency of the United States, or on the petition of any other interested person, including an application for design certification under subpart B of part 52 of this chapter.

25. In subpart H, §§ 2.811 through 2.819 are added to read as follows:

§ 2.811 Filing of standard design certification application; required copies.

(a) *Serving of applications.* The signed original of an application for a standard design certification, including all amendments to the applications must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by facsimile; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail at EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent.

(b) *Form of application.* Each original of an application and an amendment of an application must meet the requirements in § 2.813.

(c) *Capability to provide additional copies.* The applicant shall maintain the capability to generate additional copies of the general information and the safety analysis report, or part thereof or amendment thereto, for subsequent distribution in accordance with the written instructions of the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate.

(d) *Public hearing copy.* In any hearing conducted under subpart O of this part for a design certification rulemaking, the applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding, and shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements of this part.

(e) *Pre-application consultation.* A prospective applicant for a standard design certification may consult with the NRC before filing an application by writing to the Director, New, Research and Test Reactors Program, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with respect to the subject matters listed in § 2.802(a)(1)(i) through (iii) of this chapter. A prospective petitioner also may telephone the Rules and Directives Branch on (301) 415-7163, or toll free on (800) 368-5642, or send e-mail to NRCREP@nrc.gov on these subject matters. In addition, a prospective applicant may confer informally with the NRC staff BEFORE filing an application for a standard design certification, and the limitations in § 2.802(a)(2) do not apply.

§ 2.813 Written communications.

(a) *General requirements.* All correspondence, reports, and other written communications from the applicant to the Nuclear Regulatory Commission concerning the regulations in this subpart, and parts 50, 52, and 100 of this chapter must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by

visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail at EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(b) *Form of communications.* All paper copies submitted to meet the requirements set forth in paragraph (a) of this section must be typewritten, printed or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements imposed on paper submissions may be granted for the submission of micrographic, photographic, or similar forms.

(c) *Regulation governing submission.* An applicant submitting correspondence, reports, and other written communications under the regulations of this chapter is requested but not required to cite whenever practical, in the upper right corner of the first page of the submission, the specific regulation or other basis requiring submission.

§ 2.815 Docketing and acceptance review.

(a) Each application for a standard design certification will be assigned a docket number. However, to allow a determination as to whether an application is complete and acceptable for docketing, it will be initially treated as a tendered application. A copy of the tendered application will be available for public inspection at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room. Generally, the determination on acceptability for docketing will be made within a period of 30 days. The Commission may decide to determine acceptability on the basis of the technical adequacy of the application as well as its completeness.

(b) If the Commission determines that a tendered application is complete and acceptable for docketing, a docket number will be assigned to the application or part thereof, and the applicant will be notified of the determination.

§ 2.817 Withdrawal of application.

(a) The Commission may permit an applicant to withdraw an application for a standard design certification before the issuance of a notice of proposed rulemaking on such terms and conditions as the Commission may prescribe, or may, on receiving a request for withdrawal of an application, deny the application or dismiss it without prejudice. The NRC will publish in the *Federal Register* a document withdrawing the application, if the notice of receipt of the application, an advance notice of proposed rulemaking, or a notice of proposed rulemaking for the standard design certification has been previously published in the *Federal Register*. If the notice of receipt, advance notice of proposed rulemaking or notice of proposed rulemaking was published on the NRC Web site, then the notice of action on the withdrawal will also be published on the NRC Web site.

(b) The withdrawal of an application does not authorize the removal of any document from the files of the Commission.

§ 2.819 Denial of application for failure to supply information.

(a) The Commission may deny an application for a standard design certification if an applicant fails to respond to a request for additional information within 30 days from the date of the request, or within such other time as may be specified.

(b) If the Commission denies an application because the applicant has failed to respond in a timely fashion to a request for additional information, the NRC will publish in the *Federal Register* a notice of denial and will notify the applicant with a simple statement of the grounds of denial. If a notice of receipt of application, advance notice of proposed rulemaking, or notice of

proposed rulemaking for a standard design certification was published on the NRC Web site, then the notice of action on the withdrawal will also be published on the NRC Web site.

**PART 10 - CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR
ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY
INFORMATION OR AN EMPLOYMENT CLEARANCE**

26. The authority citation for Part 10 continues to read as follows:

AUTHORITY: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O. 10450, 3 CFR parts 1949-1953 COMP., p. 936, as amended; E.O. 10865, 3 CFR 1959-1963 COMP., p. 398, as amended; 3 CFR Table 4; E.O. 12968, 3 CFR 1995 COM., p. 396.

27. In § 10.1, paragraphs (a)(1) and (a)(2) are revised and paragraph (a)(3) is added to read as follows:

§ 10.1 Purpose.

(a) * * *

(1) The eligibility of individuals who are employed by or applicants for employment with NRC contractors, agents, and other individuals who are NRC employees or applicants for NRC employment, and other persons designated by the Deputy Executive Director for Information Services and Administration and Chief Information Officer of the NRC, for access to Restricted Data under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, or for access to national security information;

(2) The eligibility of NRC employees, or the eligibility of applicants for employment with the NRC, for employment clearance; and

(3) The eligibility of individuals who are employed by or are applicants for employment with NRC licensees, certificate holders, holders of standard design approvals under part 52 of this chapter, applicants for licenses, certificates, and NRC approvals, and others who may require access related to a license, certificate, or NRC approval, or other activities as the Commission may determine, for access to Restricted Data under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, or for access to national security information.

* * * **

28. In § 10.2, paragraph (b) is revised to read as follows:

§ 10.2 Scope.

* * * **

(b) NRC licensees, certificate holders and holders of standard design approvals under part 52 of this chapter, applicants for licenses, certificates, and standard design approvals under part 52 of this chapter, and their employees (including consultants) and applicants for employment (including consulting);

* * * **

**PART 19 - NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS;
INSPECTION AND INVESTIGATIONS**

29. The authority citation for Part 19 is revised to read as follows:

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282, 2297f); sec. 201,

88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 19.32 is also issued under sec. 401, 88 Stat. 1254 (42 U.S.C. 2000d, 42 U.S.C. 5891).

30. Section 19.1 is revised to read as follows:

§ 19.1 Purpose.

The regulations in this part establish requirements for notices, instructions, and reports by licensees and regulated entities to individuals participating in NRC-licensed and regulated activities and options available to these individuals in connection with Commission inspections of licensees and regulated entities, and to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, titles II and IV of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder. The regulations in this part also establish the rights and responsibilities of the Commission and individuals during interviews compelled by subpoena as part of agency inspections or investigations under section 161c of the Atomic Energy Act of 1954, as amended, on any matter within the Commission's jurisdiction.

31. Section 19.2 is revised to read as follows:

§ 19.2 Scope.

(a) The regulations in this part apply to:

(1) All persons who receive, possess, use, or transfer material licensed by the NRC under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility under parts 50 or 52 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) under part 72 of this chapter, and in accordance with 10 CFR 76.60

to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter;

(2) All applicants for and holders of licenses (including construction permits and early site permits) under parts 50, 52, and 54 of this chapter;

(3) All applicants for and holders of a standard design approval under subpart E of part 52; and

(4) All applicants for a standard design certification under subpart B of part 52 of this chapter, and those (former) applicants whose designs have been certified under that subpart.

(b) The regulations in this part regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the NRC other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued under 10 CFR 2.702.

32. In § 19.3 the definitions of *License* and *Worker* are revised, and the definitions of *Regulated entities* and *Regulated activities* are added to read as follows:

§ 19.3 Definitions.

* * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to manufacture, construct and/or operate a production or utilization facility under parts 50, 52, or 54 of this chapter.

* * * *

Regulated activities means any activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or any title of the Energy Reorganization Act of 1972, as amended.

Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an applicant for or holder of a standard design approval under subpart E of part 52 of this chapter or a standard design certification under subpart B of part 52 of this chapter.

* * * * *

Worker means an individual engaged in activities licensed or regulated by the Commission and controlled by a licensee or regulated entity, but does not include the licensee or regulated entity.

33. In § 19.11, paragraph (c) is removed and reserved, and the introductory text of paragraph (a), and paragraphs (b), (d), and (e) are revised, and paragraphs (f) and (g) are added to read as follows:

§ 19.11 Posting of notices to workers.

(a) Each licensee (except for a holder of an early site permit under subpart A of part 52 of this chapter, or a holder of a manufacturing license under subpart F of part 52 of this chapter) shall post current copies of the following documents:

* * * * *

(b) Each applicant for and holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, each applicant for a standard design certification under subpart B of part 52 of this chapter, and each applicant for and holder of a manufacturing license under subpart F of part 52 of this chapter shall post:

(1) The regulations in this part;

(2) The operating procedures applicable to the activities regulated by the NRC which are being conducted by the applicant or holder; and

(3) Any notice of violation, proposed imposition of civil penalty, or order issued under subpart B of part 2 of this chapter, and any response from the applicant or holder.

(c) **[Reserved]**

(d) If posting of a document specified in paragraphs (a)(1), (2) or (3), or (b)(1) or (2) of this section is not practicable, the licensee or regulated entity may post a notice which describes the document and states where it may be examined.

(e)(1) Each licensee, each applicant for a specific license, each applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, and each applicant for a standard design certification under subpart B of part 52 of this chapter shall prominently post NRC Form 3, "Notice to Employees," dated August 1997. Later versions of NRC Form 3 that supersede the August 1997 version shall replace the previously posted version within 30 days of receiving the revised NRC Form 3 from the Commission.

(2) Additional copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-5877, via e-mail to forms@nrc.gov, or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the home page.

(f) Documents, notices, or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in NRC-licensed or regulated activities to observe them on the way to or from any particular licensed or regulated activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(g) Commission documents posted under paragraphs (a)(4) or (b)(3) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's or regulated entity's response, if any, shall be posted within 2 working days after

dispatch by the licensee or regulated entity. These documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

34. Section 19.14 is revised to read as follows:

§ 19.14 Presence of representatives of licensees and regulated entities, and workers during inspections.

(a) Each licensee, applicant for a license, applicant for or holder of a standard design approval under subpart E of part 52, applicant for an early site permit under subpart A of part 52, and applicant for a standard design certification under subpart B of part 52 shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records under the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee, regulated entity, or the licensee's or regulated entity's representative may accompany Commission inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee or regulated entity shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in NRC-licensed or regulated activities under control of the licensee or regulated entity, and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees or regulated entities, and workers may accompany the inspectors during different phases of an inspection if there is no resulting

interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee or regulated entity, and the workers' representative an individual who is not routinely engaged in licensed or regulated activities under control of the license or regulated entity (for example, a consultant to the licensee, the regulated entity, or the workers' representative), shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Commission inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or regulated entity to enter that area.

35. Section 19.20 is revised to read as follows:

§ 19.20 Employee protection.

Employment discrimination by a licensee, a holder of a certificate of compliance issued under part 76 or regulated entity subject to the requirements in this part as delineated in § 19.2(a), or a contractor or subcontractor of a licensee, a holder of a certificate of compliance issued under part 76, or regulated entity subject to the requirements in this part as delineated in § 19.2(a), against an employee for engaging in protected activities under this part or parts 30, 40, 50, 52, 54, 60, 61, 63, 70, 72, 76, or 150 of this chapter is prohibited.

36. Section 19.31 is revised to read as follows:

§ 19.31 Application for exemptions.

The Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law, will not result in undue hazard to life and property.

37. Section 19.32 is revised to read as follows:

§ 19.32 Discrimination prohibited.

No person shall on the grounds of sex be excluded from participation in, be denied a license, be denied the benefit of, or be subjected to discrimination under any program or activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or under any title of the Energy Reorganization Act of 1974, as amended. This provision will be enforced through agency provisions and regulations similar to those already established, with respect to racial and other discrimination, under Title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

38. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

39. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 52, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under § 35.75, or to exposure from voluntary participation in medical research programs.

40. In § 20.1401 paragraph (a) is revised to read as follows:

§ 20.1401 General provisions and scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, and 72 of this chapter, and release of part of a facility or site for unrestricted use in accordance with § 50.83 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. For high-level and low-level waste disposal facilities (10 CFR parts 60, 61, and 63), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to appendix A to 10 CFR part 40 or the uranium solution extraction facilities.

* * * * *

41. In § 20.2203, paragraphs (c) and (d) are revised to read as follows:

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

* * * * *

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

(d) All licensees, other than those holding an operating license or a combined license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing either by mail addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail to EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. A copy should be sent to the appropriate NRC Regional Office listed in appendix D to this part.

PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

42. The authority citation for Part 21 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C. 2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended 1246 (42 U.S.C. 5841, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

43. In § 21.2, paragraphs (a), (b), and (c) are revised to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise, in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to:

(1) Each individual, partnership, corporation, or other entity applying for or holding a license or permit under the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and each director and responsible officer of such a licensee;

(2) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, that constructs a production or utilization facility licensed for the manufacture, construction, or operation under parts 50 or 52 of this chapter, an ISFSI for the storage of spent fuel licensed under part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under

part 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or part 72 of this chapter;

(3) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule under part 52 of this chapter; or supplying basic components with respect to that design certification, and each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, whose application for design certification has been granted under part 52 of this chapter, or who has supplied or is supplying basic components with respect to that design certification;

(4) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for or holding a standard design approval under part 52 of this chapter; or supplies basic components with respect to a regulatory approval under part 52 of this chapter;

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 of this chapter or a combined license under part 52 of this chapter (for the period of construction until the date that the Commission authorizes fuel load and operation under § 52.103 of this chapter), or to manufacture a facility under part 52 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under §50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50 or part 52 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72,

50.73, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

* * * * *

44. In Section 21.3 the definitions of *basic component*, *defect*, *deviation*, and *substantial safety hazard* are revised to read as follows:

§ 21.3 Definitions.

* * * * *

Basic component. (1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

- (A) The integrity of the reactor coolant pressure boundary;
- (B) The capability to shut down the reactor and maintain it in a safe-shutdown condition;

or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

(2) When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the

design certification or regulatory approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

- (i) The integrity of the reactor coolant pressure boundary;
- (ii) The capability to shut down the reactor and maintain it in a safe-shutdown condition;

or

(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an ESP application under part 52 of this chapter, whether these services are performed by the component supplier or others.

* * * * *

Defect means:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard;

(2) The installation, use, or operation of a basic component containing a defect as defined in this section;

(3) A deviation in a portion of a facility subject to the early site permit, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter; or

(5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

Deviation means a departure from the technical requirements included in a procurement document, or specified in ESP information, a design certification or standard design approval.

* * * * *

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

45. Section 21.5 is revised to read as follows:

§ 21.5 Communications.

Except where otherwise specified in this part, written communications and reports concerning the regulations in this part must be addressed to the NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail to EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee or permit holder, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

46. In § 21.21 paragraphs (a)(3), (a)(3)(i), (d)(1)(i), (d)(1)(ii), and (d)(4)(vi) are revised and paragraph (d)(4)(ix) is added to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) * * *

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraphs (a)(1) or (a)(2) of this section if the manufacture,

construction or operation of a facility or activity, a basic component supplied for such facility or activity, or the design certification or regulatory approval under part 52 of this chapter—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable regulation, order, or license of the Commission or standard design approval under part 52 of this chapter, relating to a substantial safety hazard, or

* * * * *

(d)(1)* * *

(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or regulatory approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

(4)* * *

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

* * * * *

(ix) In the case of an early site permit, the entities to whom an early site permit was sold or transferred.

* * * * *

47. In § 21.51 paragraph (a)(4) is added and paragraph (b) is revised to read as follows:

§ 21.51 Maintenance and inspection of records.

(a)* * *

(4) Applicants for standard design certification under subpart C of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.

(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

48. In § 21.61, paragraph (b) is revised to read as follows:

§ 21.61 Failure to notify.

* * * * *

(b) Any NRC licensee (including a holder of a permit), applicant for a design certification under part 52 of this chapter during the pendency of its application, applicant for a design certification after Commission adoption of a final design certification rule for that design, or applicant for or holder of a standard design approval under part 52 of this chapter subject to the regulations in this part who fail to provide the notice required by § 21.21, or otherwise fails to

comply with the applicable requirements of this part shall be subject to a civil penalty as provided by Section 234 of the Atomic Energy Act of 1954, as amended.

* * * * *

PART 25 - ACCESS AUTHORIZATION FOR LICENSEE PERSONNEL

49. The authority citation for Part 25 continues to read as follows:

AUTHORITY: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); E.O. 10865, as amended, 3 CFR 1959-1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12829, 3 CFR, 1993 Comp., p. 570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p. 333 as amended by E.O. 13292, 3 CFR 2004 Comp., p. 196; E.O. 12968, 3 CFR, 1995 Comp, p. 396.

Appendix A also issued under 96 Stat. 1051 (31 U.S.C. 9701).

50. The heading of Part 25 is revised to read as follows:

PART 25 - ACCESS AUTHORIZATION

51. In § 25.35, paragraph (a) is revised to read as follows:

§ 25.35 Classified visits.

(a) The number of classified visits must be held to a minimum. The licensee, certificate holder, applicant for a standard design certification under part 52 of this chapter (including an applicant after the Commission has adopted a final standard design certification rule under part 52 of this chapter), or other facility, or an applicant for or holder of a standard design approval under part 52 of this chapter shall determine that the visit is necessary and that the purpose of the visit cannot be achieved without access to, or disclosure of, classified

information. All classified visits require advance notification to, and approval of, the organization to be visited. In urgent cases, visit information may be furnished by telephone and confirmed in writing.

* * * * *

PART 26 - FITNESS FOR DUTY PROGRAMS

52. The authority citation for Part 26 continues to read as follows:

AUTHORITY: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201, 2297f); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

53. In § 26.2, the introductory text of paragraph (a), and paragraph (c) are revised to read as follows:

§ 26.2 Scope.

(a) The regulations in this part apply to licensees authorized to operate a nuclear power reactor, including a holder of a combined license after the Commission makes the finding under § 52.103(g) of this chapter, and licensees who are authorized to possess or use formula quantities of SSNM, or to transport formula quantities of SSNM. Each licensee shall implement a fitness-for-duty program which complies with this part. The provisions of the fitness-for-duty program must apply to all persons granted unescorted access to nuclear power plant protected areas, to licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures, and to SSNM licensee and transporter personnel who:

* * * * *

(c) Certain regulations in this part apply to licensees holding permits to construct a nuclear power plant, including a holder of a combined license before the date that the Commission makes the finding under § 52.103(g) of this chapter, holders of manufacturing licenses under part 52, and persons authorized to conduct the activities under § 50.10(e)(3) of this chapter. Each licensee with a construction permit, a combined license before the Commission makes the finding under § 52.103(g) of this chapter, a manufacturing license, or person authorized to conduct the activities under § 50.10(e)(3) of this chapter, with a plant or reactor under active construction or manufacture, shall—

- (1) Comply with §§ 26.10, 26.20, 26.23, 26.70, and 26.73;
- (2) Implement a chemical testing program, including random tests; and
- (3) Make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and recordkeeping.

* * * * *

54. In § 26.10, paragraph (a) is revised to read as follows:

§ 26.10 General performance objectives.

* * * * *

(a) Provide reasonable assurance that nuclear power plant personnel, personnel of a holder of a manufacturing license, personnel of a person authorized to conduct activities under § 50.10(e)(3) of this chapter, transporter personnel, and personnel of licensees authorized to possess or use formula quantities of SSNM, will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

* * * * *

55. In Appendix A of Part 26, paragraph (1) of Section 1.1 of Subpart A is revised to read as follows:

Appendix A to Part 26 – Guidelines for Drug and Alcohol Testing Programs

1.1 Applicability.

(1) These guidelines apply to licensees authorized to operate nuclear power reactors, including a holder of a combined license after the Commission makes the finding under § 52.103(g) of this chapter, and licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM).

* * * * *

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

56. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and appendix Q also issued under sec. 102, Pub. L. 91-190, 83

Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

57. In Section 50.2, definitions of *applicant*, *license*, *licensee*, and *prototype plant*, are added to read as follows:

§ 50.2 Definitions.

* * * * *

Applicant means a person or an entity applying for a license, permit, or other form of Commission permission or approval under this part or part 52 of this chapter.

* * * * *

License means a license, including a construction permit or operating license under this part, an early site permit, combined license or manufacturing license under part 52 of this chapter, or a renewed license issued by the Commission under this part, part 52, or part 54 of this chapter.

Licensee means a person who is authorized to conduct activities under a license issued by the Commission.

* * * * *

Prototype plant means a nuclear reactor that is used to test design features, such as the testing required under § 50.43(e). The prototype plant is similar to a first-of-a-kind or standard plant design in all features and size, but may include additional safety features to protect the public and the plant staff from the possible consequences of accidents during the testing period.

* * * * *

58. In § 50.10 the introductory text of paragraphs (b) and (c), and paragraphs (e)(1), (e)(2), and (e)(3) are revised to read as follows:

§ 50.10 License required.

* * * * *

(b) No person shall begin the construction of a production or utilization facility on a site on which the facility is to be operated until either a construction permit under this part, or a combined license under subpart C of part 52 of this chapter has been issued. As used in this paragraph, the term “construction” includes pouring the foundation for, or the installation of, any portion of the permanent facility on the site, but does not include:

* * * * *

(c) Notwithstanding the provisions of paragraph (b) of this section, and subject to paragraphs (d) and (e) of this section, no person shall effect commencement of construction of a production or utilization facility subject to the provisions of § 51.20(b) of this chapter on a site on which the facility is to be operated until an early site permit, construction permit, or combined license has been issued. As used in this paragraph, the term “commencement of construction” means any clearing of land, excavation or other substantial action that would adversely affect the environment of a site, but does not include:

* * * * *

(e)(1) The Director of Nuclear Reactor Regulation may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b)(2) or (3), or § 50.22 or is a testing facility, or an applicant for a combined license to conduct the following activities:

(i) Preparation of the site for construction of the facility (including activities as clearing, grading, construction of temporary access roads and borrow areas);

(ii) Installation of temporary construction support facilities (including items such as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings);

(iii) Excavation for facility structures;

(iv) Construction of service facilities (including facilities such as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines, and sanitary sewerage treatment facilities); and

(v) The construction of structures, systems and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

(2) No authorization shall be granted unless the staff has completed a final environmental impact statement on the issuance of the construction permit or combined license as required by subpart A of part 51 of this chapter. An authorization shall be granted only after the presiding officer in the proceeding on the construction permit or combined license application:

(i) Has made all the findings required by §§ 51.104(b), 51.105, and 51.107 of this chapter to be made before issuance of the construction permit, or combined license for the facility; and

(ii) Has determined that, based upon the available information and review to date, there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type proposed from the standpoint of radiological health and safety considerations under the Act and regulations issued by the Commission.

(3)(i) The Director of Nuclear Reactor Regulation may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b)(2) or (3), or § 50.22 or is a testing facility, or an applicant for a combined license to conduct, in addition to the activities described in paragraph (e)(1) of this section, the installation of structural foundations, including any necessary subsurface preparation, for structures, systems, and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

(ii) Such an authorization, which may be combined with the authorization described in paragraph (e)(1) of this section, or may be granted at a later time, shall be granted only after the presiding officer in the proceeding on the construction permit or combined license application has, in addition to making the findings and determinations required by paragraph (e)(2) of this section, determined that there are no unresolved safety issues relating to the additional activities that may be authorized under this paragraph that would constitute good cause for withholding authorization.

* * * * *

59. Section 50.23 is revised to read as follows:

§ 50.23 Construction permits.

A construction permit for the construction of a production or utilization facility will be issued before the issuance of a license if the application is otherwise acceptable, and will be converted upon completion of the facility and Commission action, into a license as provided in § 50.56. However, if a combined license for a nuclear power reactor is issued under part 52 of this chapter, the construction permit and operating license are deemed to be combined in a single license. A construction permit for the alteration of a production or utilization facility will be

issued before the issuance of an amendment of a license, if the application for amendment is otherwise acceptable, as provided in § 50.91.

60. In § 50.30, the section heading and paragraphs (a)(1), (a)(3), (a)(5), (a)(6), (b), (e), and (f) are revised to read as follows:

§ 50.30 Filing of application; oath or affirmation.

(a)* * *

(1) Each filing of an application for a standard design approval or license to construct and/or operate, or manufacture, a production or utilization facility (including an early site permit, combined license, and manufacturing license under part 52 of this chapter), and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission in accordance with § 50.4 or § 52.3 of this chapter, as applicable.

* * * * *

(3) Each applicant for a construction permit under this part, or an early site permit, combined license, or manufacturing license under part 52 of this chapter, shall, upon notification by the Atomic Safety and Licensing Board appointed to conduct the public hearing required by the Atomic Energy Act, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by the Atomic Safety and Licensing Board. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the U.S. Nuclear Regulatory Commission as specified in § 50.4 or § 52.3 of this chapter, as applicable.

* * * * *

(5) At the time of filing an application, the Commission will make available at the NRC Web site, <http://www.nrc.gov>, a copy of the application, subsequent amendments, and other

records pertinent to the matter which is the subject of the application for public inspection and copying.

(6) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 50.4 or § 52.3 of this chapter, as applicable, to enable the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate, to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation.* Each application for a standard design approval or license, including, whenever appropriate, a construction permit or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

* * * * *

(e) *Filing Fees.* Each application for a standard design approval or production or utilization facility license, including, whenever appropriate, a construction permit or early site permit, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in part 170 of this chapter. No fee will be required to accompany an application for renewal, amendment, or termination of a construction permit, operating license, combined license, or manufacturing license, except as provided in § 170.21 of this chapter.

(f) *Environmental report.* An application for a construction permit, operating license, early site permit, combined license, or manufacturing license for a nuclear power reactor, testing facility, fuel reprocessing plant, or other production or utilization facility whose construction or operation may be determined by the Commission to have a significant impact in the environment, shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

61. In § 50.33, paragraphs (f)(3) and (f)(4) are redesignated as (f)(4) and (f)(5), respectively, and are revised, a new paragraph (f)(3) is added, and paragraphs (g) and (k)(1) are revised to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(f)* * *

(3) If the application is for a combined license under subpart C of part 52 of this chapter, the applicant shall submit the information described in paragraphs (f)(1) and (f)(2) of this section.

(4) Each application for a construction permit, operating license, or combined license submitted by a newly-formed entity organized for the primary purpose of constructing and/or operating a facility must also include information showing:

(i) The legal and financial relationships it has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(5) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(g) If the application is for an operating license or combined license for a nuclear power reactor, or if the application is for an early site permit and contains plans for coping with

emergencies under § 52.17(b)(2)(ii) of this chapter, the applicant shall submit radiological emergency response plans of State and local governmental entities in the United States that are wholly or partially within the plume exposure pathway Emergency Planning Zone (EPZ)³, as well as the plans of State governments wholly or partially within the ingestion pathway EPZ.⁴

Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ shall consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 MW thermal. The plans for the ingestion pathway shall focus on such actions as are appropriate to protect the food ingestion pathway.

* * * * *

(k)(1) For an application for an operating license or combined license for a production or utilization facility, information in the form of a report, as described in § 50.75, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

* * * * *

³Emergency Planning Zones (EPZs) are discussed in NUREG-0396, EPA 520/1-78-016, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-Water Nuclear Power Plants," December 1978.

⁴If the State and local emergency response plans have been previously provided to the NRC for inclusion in the facility docket, the applicant need only provide the appropriate reference to meet this requirement.

62. In § 50.34, the section heading, the introductory text of paragraph of (a)(1), paragraphs (a)(1)(ii)(E) and (a)(12), the introductory text of paragraph (b), paragraphs (b)(10) and (b)(11), and paragraphs (c), (d), and (e), the introductory text of paragraphs (f) and (f)(1), and paragraphs (g), and (h)(1)(ii) are revised to read as follows:

§ 50.34 Contents of construction permit and operating license applications; technical information.

(a) * * *

(1) Stationary power reactor applicants for a construction permit who apply on or after January 10, 1997, shall comply with paragraph (a)(1)(ii) of this section. All other applicants for a construction permit shall comply with paragraph (a)(1)(i) of this section.

* * * * *

(ii) * * *

(E) With respect to operation at the projected initial power level, the applicant is required to submit information prescribed in paragraphs (a)(2) through (a)(8) of this section, as well as the information required by paragraph (a)(1)(i) of this section, in support of the application for a construction permit.

* * * * *

(12) On or after January 10, 1997, stationary power reactor applicants who apply for a construction permit, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria in appendix S to this part.

(b) *Final safety analysis report.* Each application for an operating license shall include a final safety analysis report. The final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and shall include the following:

* * * * *

(10) On or after January 10, 1997, stationary power reactor applicants who apply for an operating license, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria of appendix S to this part. However, for those operating license applicants and holders whose construction permit was issued before January 10, 1997, the earthquake engineering criteria in section VI of appendix A to part 100 of this chapter continues to apply.

(11) On or after January 10, 1997, stationary power reactor applicants who apply for an operating license, shall provide a description and safety assessment of the site and of the facility as in § 50.34(a)(1)(ii). However, for either an operating license applicant or holder whose construction permit was issued before January 10, 1997, the reactor site criteria in part 100 of this chapter and the seismic and geologic siting criteria in appendix A to part 100 of this chapter continues to apply.

(c) Each application for an operating license for a production or utilization facility must include a physical security plan. The plan must describe how the applicant will meet the requirements of part 73 of this chapter (and part 11 of this chapter, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(d) *Safeguards contingency plan.* Each application for an operating license for a production or utilization facility that will be subject to §§ 73.50, 73.55, or § 73.60 of this chapter, must include a licensee safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the

applicant's possession and control. Each application for such a license shall include the first four categories of information contained in the applicant's safeguards contingency plan. (The first four categories of information as set forth in appendix C to 10 CFR part 73 of this chapter are Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix. The fifth category of information, Procedures, does not have to be submitted for approval.)⁹

(e) *Protection against unauthorized disclosure.* Each applicant for an operating license for a production or utilization facility, who prepares a physical security plan, a safeguards contingency plan, or a guard qualification and training plan, shall protect the plans and other related safeguards information against unauthorized disclosure in accordance with the requirements of § 73.21 of this chapter, as appropriate.

(f) *Additional TMI-related requirements.* In addition to the requirements of paragraph (a) of this section, each applicant for a light-water-reactor construction permit or manufacturing license whose application was pending as of February 16, 1982, shall meet the requirements in paragraphs (f)(1) through (3) of this section. This regulation applies to the pending applications by Duke Power Company (Perkins Nuclear Station Units 1, 2, and 3), Houston Lighting & Power Company (Allens Creek Nuclear Generating Station, Unit 1), Portland General Electric Company (Pebble Springs Nuclear Plant, Units 1 and 2), Public Service Company of Oklahoma (Black Fox Station, Units 1 and 2), Puget Sound Power & Light Company (Skagit/Hanford Nuclear Power Project, Units 1 and 2), and Offshore Power Systems (License to Manufacture Floating Nuclear Plants). The number of units that will be specified in the manufacturing license above, if issued, will be that number whose start of manufacture, as defined in the license application, can practically begin within a 10-year period commencing on the date of issuance of the manufacturing license, but in no event will that number be in excess of ten. The

⁹A physical security plan that contains all the information required in both § 73.55 and appendix C to part 73 of this chapter satisfies the requirement for a contingency plan.

manufacturing license will require the plant design to be updated no later than 5 years after its approval. Paragraphs (f)(1)(xii), (2)(ix), and (3)(v) of this section, pertaining to hydrogen control measures, must be met by all applicants covered by this regulation. However, the Commission may decide to impose additional requirements and the issue of whether compliance with these provisions, together with 10 CFR 50.44 and criterion 50 of appendix A to 10 CFR part 50, is sufficient for issuance of that manufacturing license which may be considered in the manufacturing license proceeding. In addition, each applicant for a design certification, design approval, combined license, or manufacturing license under part 52 of this chapter shall demonstrate compliance with the technically relevant portions of the requirements in paragraphs (f)(1) through (3) of this section.

(1) To satisfy the following requirements, the application shall provide sufficient information to describe the nature of the studies, how they are to be conducted, estimated submittal dates, and a program to ensure that the results of these studies are factored into the final design of the facility. For licensees identified in the introduction to paragraph (f) of this section, all studies must be completed no later than 2 years following the issuance of the construction permit or manufacturing license.¹⁰ For all other applicants, the studies must be submitted as part of the final safety analysis report.

* * * * *

(g) *Combustible gas control.* All applicants for a reactor construction permit or operating license whose application is submitted after October 16, 2003, shall include the analyses, and the descriptions of the equipment and systems required by § 50.44 as a part of their application.

(h)* * *

¹⁰ Alphanumeric designations correspond to the related action plan items in NUREG 0718 and NUREG 0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident." They are provided herein for information only.

(1)* * *

(ii) Applications for light-water-cooled nuclear power plant construction permits docketed after May 17, 1982, shall include an evaluation of the facility against the SRP in effect on May 17, 1982, or the SRP revision in effect six months before the docket date of the application, whichever is later.

* * * * *

63. Section 50.34a is revised to read as follows:

§ 50.34a Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors.

(a) An application for a construction permit shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, including expected operational occurrences. In the case of an application filed on or after January 2, 1971, the application shall also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as is reasonably achievable. The term “as low as is reasonably achievable” as used in this part means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest. The guides set out in appendix I to this part provide numerical guidance on design objectives for light-water-cooled nuclear power reactors to meet the requirements that radioactive material in effluents released to unrestricted areas be kept as low as is reasonably achievable. These numerical guides for design objectives and limiting conditions for operation are not to be construed as radiation protection standards.

(b) Each application for a construction permit shall include:

(1) A description of the preliminary design of equipment to be installed under paragraph (a) of this section;

(2) An estimate of:

(i) The quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations; and

(ii) The quantity of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations.

(3) A general description of the provisions for packaging, storage, and shipment offsite of solid waste containing radioactive materials resulting from treatment of gaseous and liquid effluents and from other sources.

(c) Each application for an operating license shall include:

(1) A description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) A revised estimate of the information required in paragraph (b)(2) of this section if the expected releases and exposures differ significantly from the estimates submitted in the application for a construction permit.

(d) Each application for a combined license under part 52 of this chapter shall include:

(1) A description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) An estimate of the information required in paragraph (b)(2) of this section.

(e) Each application for a design approval, a design certification, or a manufacturing license under part 52 of this chapter shall include:

(1) A description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) An estimate of the information required in paragraph (b)(2) of this section.

64. In § 50.36, current paragraphs (c), (d), and (e) are redesignated as paragraphs (d), (e), and (f), respectively, and a new paragraph (c) is added to read as follows:

§ 50.36 Technical specifications.

* * * * *

(c) Each applicant for a design certification under part 52 of this chapter shall include in its application proposed generic technical specifications in accordance with the requirements of this section for the portion of the plant that is within the scope of the design certification application.

* * * * *

65. In § 50.36a, the introductory text of paragraph (a) is revised to read as follows:

§ 50.36a Technical specifications on effluents from nuclear power reactors.

(a) To keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable, each licensee of a nuclear power reactor and each applicant for a design certification will include technical specifications that, in addition to requiring compliance with applicable provisions of § 20.1301 of this chapter, require that:

* * * * *

66. Section 50.37 is revised to read as follows:

§ 50.37 Agreement limiting access to Classified Information.

As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license, construction permit, early site permit, or standard design approval, or before the Commission has adopted a final standard design certification rule under part 52, the applicant shall agree in writing that it will not permit any individual to have access to any facility to possess restricted data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license, or construction permit, or standard design approval.

67. The undesignated center heading before § 50.40 is revised as follows:

Standards for Licenses, Certifications, and Regulatory Approval

68. Section 50.40 is revised to read as follows:

§ 50.40 Common standards.

In determining that a construction permit or operating license in this part, or early site permit, combined license, or manufacturing license in part 52 of this chapter will be issued to an applicant, the Commission will be guided by the following considerations:

(a) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in part 20 of this chapter, and that the health and safety of the public will not be endangered.

(b) The applicant for a construction permit, operating license, combined license, or manufacturing license is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter. However, no consideration of financial qualification is necessary for an electric utility applicant for an operating license for a utilization facility of the type described in § 50.21(b) or § 50.22 or for an applicant for a manufacturing license.

(c) The issuance of a construction permit, operating license, early site permit, combined license, or manufacturing license to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.

(d) Any applicable requirements of subpart A of 10 CFR part 51 have been satisfied.

69. In § 50.43, the section heading, the introductory paragraph, and paragraph (d) are revised, and paragraph (e) is added to read as follows:

§ 50.43 Additional standards and provisions affecting class 103 licenses and certifications for commercial power.

In addition to applying the standards set forth in §§ 50.40 and 50.42, paragraphs (a) through (e) of this section apply in the case of a class 103 license for a facility for the generation of commercial power. For a design certification under part 52 of this chapter, only paragraph (e) of this section applies.

* * * * *

(d) Nothing shall preclude any government agency, now or hereafter authorized by law to engage in the production, marketing, or distribution of electric energy, if otherwise qualified, from obtaining a construction permit or operating license under this part, or a combined license under part 52 of this chapter for a utilization facility for the primary purpose of producing electric energy for disposition for ultimate public consumption.

(e) Applications for a design certification, combined license, manufacturing license, or operating license that propose nuclear reactor designs which differ significantly from light-water reactor designs that were licensed before 1997, or use simplified, inherent, passive, or other innovative means to accomplish their safety functions, will be approved only if:

(1)(i) The performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof;

(ii) Interdependent effects among the safety features of the design are acceptable, as demonstrated by analysis, appropriate test programs, experience, or a combination thereof; and

(iii) Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions; or

(2) There has been acceptable testing of a prototype plant over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. If a prototype plant is used to comply with the testing requirements, then the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to protect the public and the plant staff from the possible consequences of accidents during the testing period.

70. Section 50.45 is revised to read as follows:

§ 50.45 Standards for construction permits, operating licenses, and combined licenses.

(a) An applicant for an operating license or an amendment of an operating license who proposes to construct or alter a production or utilization facility will be initially granted a construction permit if the application is in conformity with and acceptable under the criteria of §§ 50.31 through 50.38, and the standards of §§ 50.40 through 50.43, as applicable.

(b) An applicant for a combined license or an amendment of a combined license under part 52 of this chapter who proposes to construct a utilization facility will be granted the combined license or amendment if the application is in conformity with and acceptable under the criteria of §§ 50.31 through 50.38, and the standards of §§ 50.40 through 50.43, as applicable.

(c) A holder of a combined license who proposes, after the Commission makes the finding under § 52.103(g) of this chapter, to alter the licensed facility will be initially granted either a construction permit or combined license if the application is in conformity with and acceptable under the criteria of §§ 50.31 through 50.38, and the standards of §§ 50.40 through 50.43, as applicable.

71. In § 50.46, paragraph (a)(3) is revised to read as follows:

§ 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.

(a)* * *

(3)(i) Each applicant for or holder of an operating license or construction permit issued under this part, applicant for a standard design certification under part 52 of this chapter (including an applicant after the Commission has adopted a final design certification regulation), or an applicant for or holder of a standard design approval, a combined license or a manufacturing license issued under part 52 of this chapter, shall estimate the effect of any change to or error in an acceptable evaluation model or in the application of such a model to determine if the change or error is significant. For this purpose, a significant change or error is one which results in a calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model, or is a

cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F.

(ii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a construction permit, operating license, combined license, or manufacturing license shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission at least annually as specified in § 50.4 or § 52.3 of this chapter, as applicable. If the change or error is significant, the applicant or licensee shall provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. This schedule may be developed using an integrated scheduling system previously approved for the facility by the NRC. For those facilities not using an NRC approved integrated scheduling system, a schedule will be established by the NRC staff within 60 days of receipt of the proposed schedule. Any change or error correction that results in a calculated ECCS performance that does not conform to the criteria set forth in paragraph (b) of this section is a reportable event as described in §§ 50.55(e), 50.72, and 50.73. The affected applicant or licensee shall propose immediate steps to demonstrate compliance or bring plant design or operation into compliance with § 50.46 requirements.

(iii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a standard design approval or the applicant for a standard design certification (including an applicant after the Commission has adopted a final design certification rule) shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission and to any applicant or licensee referencing the design approval or design certification at least annually as specified in § 52.3 of this chapter. If the change or error is

significant, the applicant or holder of the design approval or the applicant for the design certification shall provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. The affected applicant or holder shall propose immediate steps to demonstrate compliance or bring plant design into compliance with § 50.46 requirements.

* * * * *

72. In § 50.47, paragraph (a)(1), the introductory text of paragraph (c)(1), paragraphs (c)(1)(i) and (c)(1)(iii)(B) are revised, and paragraph (e) is added to read as follows:

§ 50.47 Emergency plans.

(a)(1)(i) Except as provided in paragraph (d) of this section, no initial operating license for a nuclear power reactor will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed nuclear power reactor operating license.

(ii) Except as provided in paragraph (e) of this section, no initial combined license under part 52 of this chapter will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed combined license.

(iii) For emergency plans submitted by an applicant under 10 CFR 52.17(b)(2)(ii), no early site permit under subpart A of part 52 of this chapter will be issued unless a finding is made by the NRC that the emergency plans provide reasonable assurance that adequate

protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed early site permit.

* * * * *

(c)(1) Failure to meet the applicable standards set forth in paragraph (b) of this section may result in the Commission declining to issue an operating license or combined license. However, the applicant will have an opportunity to demonstrate to the satisfaction of the Commission that deficiencies in the plans are not significant for the plant in question, that adequate interim compensating actions have been or will be taken promptly, or that there are other compelling reasons to permit plant operations. Where an applicant for an operating license or combined license asserts that its inability to demonstrate compliance with the requirements of paragraph (b) of this section results wholly or substantially from the decision of state and/or local governments not to participate further in emergency planning, or if an applicant cannot obtain the certifications required by § 52.79(a)(22) of this chapter, an operating license or combined license may be issued if the applicant demonstrates to the Commission's satisfaction that:

(i) The applicant's inability to comply with the requirements of paragraph (b) of this section or § 52.79(a)(22) of this chapter is wholly or substantially the result of the non-participation of state and/or local governments.

* * * * *

(iii) * * *

(B) The utility's measures designed to compensate for any deficiencies resulting from State and/or local non-participation. In making its determination on the adequacy of a utility plan, the NRC will recognize the reality that in an actual emergency, State and local government officials will exercise their best efforts to protect the health and safety of the public. The NRC will determine the adequacy of that expected response, in combination with the utility's

compensating measures, on a case-by-case basis, subject to the following guidance. In addressing the circumstance where applicant's inability to comply with the requirements of paragraph (b) of this section or § 52.79(a)(22) of this chapter, is wholly or substantially the result of non-participation of state and/or local governments, it may be presumed that in the event of an actual radiological emergency State and local officials would generally follow the utility plan. However, this presumption may be rebutted by, for example, a good faith and timely proffer of an adequate and feasible State and/or local radiological emergency plan that would in fact be relied upon in a radiological emergency.

* * * * *

(e) Notwithstanding the requirements of paragraphs (a) and (b) of this section and the provisions of § 52.103 of this chapter, a holder of a combined license under part 52 of this chapter may not load fuel or operate except as provided in accordance with appendix E to part 50 and § 50.54(gg).

73. In § 50.48, the introductory text of paragraph (a)(1) is revised to read as follows:

§ 50.48 Fire protection.

(a)(1) Each holder of an operating license issued under this part or a combined license issued under part 52 of this chapter must have a fire protection plan that satisfies Criterion 3 of appendix A to this part. This fire protection plan must:

* * * * *

74. In § 50.49, paragraph (a) is revised to read as follows:

§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

(a) Each holder of or an applicant for an operating license issued under this part, or a combined license or manufacturing license issued under part 52 of this chapter, other than a nuclear power plant for which the certifications required under § 50.82(a)(1) have been submitted, shall establish a program for qualifying the electric equipment defined in paragraph (b) of this section. For a manufacturing license, only electric equipment defined in paragraph (b) which is within the scope of the manufactured reactor must be included in the program.

* * * * *

75. In § 50.54, the introductory text, and paragraphs (a)(1), (i-1), and (o) are revised and paragraph (gg) is added to read as follows:

§ 50.54 Conditions of licenses.

The following paragraphs with the exception of paragraphs (r) and (gg) of this section are conditions in every operating license issued under this part, and the following paragraphs with the exception of paragraph (s) of this section are conditions in every combined license issued under part 52 of this chapter.

(a)(1) Each nuclear power plant or fuel reprocessing plant licensee subject to the quality assurance criteria in appendix B of this part shall implement, under § 50.34(b)(6)(ii) of this part or § 52.79 of this chapter, the quality assurance program described or referenced in the safety analysis report, including changes to that report. However, a holder of a combined license under part 52 of this chapter shall implement the quality assurance program described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for the initial loading of fuel.

* * * * *

(i-1) Within three (3) months after either the issuance of an operating license or the date that the Commission makes the finding under § 52.103(g) of this chapter for a combined license, as applicable, the licensee shall have in effect an operator requalification program. The operator requalification program must, as a minimum, meet the requirements of § 55.59(c) of this chapter. Notwithstanding the provisions of § 50.59, the licensee may not, except as specifically authorized by the Commission decrease the scope of an approved operator requalification program.

* * * * *

(o) Primary reactor containments for water cooled power reactors, other than facilities for which the certifications required under §§ 50.82(a)(1) or 52.110(a)(1) have been submitted, shall be subject to the requirements set forth in appendix J to this part.

* * * * *

(gg)(1) Notwithstanding 10 CFR 52.103, if, following the conduct of the exercise required by paragraph IV.f.2.a of appendix E to part 50 of this chapter, FEMA identifies one or more deficiencies in the state of offsite emergency preparedness, the holder of a combined license under 10 CFR 52 may operate at up to 5 percent of rated thermal power only if the Commission finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC will base this finding on its assessment of the applicant's onsite emergency plans against the pertinent standards in § 50.47 and appendix E to this part. Review of the applicant's emergency plans will include the following standards with offsite aspects:

(i) Arrangements for requesting and effectively using offsite assistance onsite have been made, arrangements to accommodate State and local staff at the licensee's near-site

Emergency Operations Facility have been made, and other organizations capable of augmenting the planned onsite response have been identified.

(ii) Procedures have been established for licensee communications with State and local response organizations, including initial notification of the declaration of emergency and periodic provision of plant and response status reports.

(iii) Provisions exist for prompt communications among principal response organizations to offsite emergency personnel who would be responding onsite.

(iv) Adequate emergency facilities and equipment to support the emergency response onsite are provided and maintained.

(v) Adequate methods, systems, and equipment for assessing and monitoring actual or potential offsite consequences of a radiological emergency condition are in use onsite.

(vi) Arrangements are made for medical services for contaminated and injured onsite individuals.

(vii) Radiological emergency response training has been made available to those offsite who may be called to assist in an emergency onsite.

(2) The condition in this paragraph, regarding operation at up to 5 percent power, ceases to apply 30 days after FEMA informs the NRC that the offsite deficiencies have been corrected, unless the NRC notifies the combined license holder before the expiration of the 30-day period that the Commission finds under paragraphs (s)(2) and (3) of this section that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

76. In § 50.55, the heading, the introductory text and paragraphs (a), (b), (c), and (e) are revised, and a new paragraph (f)(4) is added to read as follows:

§ 50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.

Each construction permit is subject to the following terms and conditions; each early site permit is subject to the terms and conditions in paragraph (f) of this section; each manufacturing license is subject to the terms and conditions in paragraphs (e) and (f) of this section; and each combined license is subject to the terms and conditions in paragraphs (a), (b), (c), (e) and (f) of this section until the date that the Commission makes the finding under § 52.103(g) of this chapter:

(a) The construction permit and combined license shall state the earliest and latest dates for completion of the construction or modification.

(b) If the proposed construction or modification of the facility is not completed by the latest completion date, the permit or license expires and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributable to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

(c) Except as modified by this section and § 50.55a, the construction permit or combined license is subject to the same conditions to which a license is subject.

* * * * *

(e)(1) *Definitions.* For purposes of this paragraph, the definitions in § 21.3 of this chapter apply.

(2) *Posting requirements.* (i) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of the regulations in this part; Section 206 of the Energy Reorganization Act of 1974 (ERA); and procedures adopted

under the regulations in this part. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(ii) If posting of the regulations in this part or the procedures adopted under the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting Section 206 of the ERA, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where the regulation, procedures, and reports may be examined.

(3) *Procedures.* Each individual, corporation, partnership, or other entity holding a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license under 10 CFR part 52 must adopt appropriate procedures to—

(i) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (e)(3)(ii) of this section, in all cases within 60 days of discovery, to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(ii) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in paragraph (e)(10) of this section. The interim report should describe the deviation or failure to comply that it is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(iii) Ensure that a director or responsible officer of the holder of a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license under 10 CFR part 52 is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (e)(3)(i) or (e)(3)(ii) of this section, if the construction or manufacture of a facility or activity, or a basic component supplied for such facility or activity—

(A) Fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission, relating to a substantial safety hazard;

(B) Contains a defect; or

(C) Undergoes any significant breakdown in any portion of the quality assurance program conducted under the requirements of appendix B to 10 CFR part 50 which could have produced a defect in a basic component. These breakdowns in the quality assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture.

(4) *Notification.*

(i) The holder of a facility construction permit subject to this part, combined license (until the Commission makes the finding under § 10 CFR 52.103(g)), and manufacturing license who obtains information reasonably indicating that the facility fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director or responsible officer or designated person as discussed in paragraph (e)(10) of this section.

(ii) The holder of a facility construction permit subject to this part or combined license who obtains information reasonably indicating the existence of any defect found in the construction or any defect found in the final design of a facility as approved and released for

construction must notify the Commission of the defect through a director or responsible officer or designated person as discussed in paragraph (e)(10) of this section.

(iii) The holder of a facility construction permit subject to this part or combined license, who obtains information reasonably indicating that the quality assurance program has undergone any significant breakdown discussed in paragraph (e)(3)(ii)(C) of this section must notify the Commission of the breakdown in the quality assurance program through a director or responsible officer or designated person as discussed in paragraph (e)(10) of this section.

(iv) A dedicating entity is responsible for identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and maintaining auditable records for the dedication process.

(v) The notification requirements of this paragraph apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the safety analysis report, construction permit, or manufacturing license. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the construction permit holder's, combined license holder's, and manufacturing license holder's evaluation and notification obligations under part 21 of this chapter, and satisfies the responsibility of individual directors or responsible officers of holders of construction permits issued under § 50.23, holders of combined licenses (until the Commission makes the finding under § 52.103 of this chapter), and holders of manufacturing licenses to report defects, and failures to comply associated with substantial safety hazards under Section 206 of the ERA. The director or responsible officer may authorize an individual to provide the notification required by this section, provided that this must not relieve the director or responsible officer of his or her responsibility under this section.

(5) *Notification — timing and where sent.* The notification required by paragraph (e)(4) of this section must consist of—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within 2 days following receipt of information by the director or responsible corporate officer under paragraph (e)(3)(iii) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in paragraph (e)(3)(ii) of this section.

(ii) Written notification submitted to the Document Control Desk, U.S. Nuclear Regulatory Commission, by an appropriate method listed in § 50.4, with a copy to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter and a copy to the appropriate NRC resident inspector within 30 days following receipt of information by the director or responsible corporate officer under paragraph (e)(3)(iii) of this section, on the identification of a defect or failure to comply.

(6) *Content of notification.* The written notification required by paragraph (e)(9)(ii) of this section must clearly indicate that the written notification is being submitted under § 50.55(e) and include the following information, to the extent known—

- (i) Name and address of the individual or individuals informing the Commission.
- (ii) Identification of the facility, the activity, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.
- (iii) Identification of the firm constructing or manufacturing the facility or supplying the basic component which fails to comply or contains a defect.
- (iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by the defect or failure to comply.

(v) The date on which the information of a defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all the basic components in use at the facility subject to the regulations in this part.

(vii) In the case of a completed reactor manufactured under part 52 of this chapter, the entities to which the reactor was supplied.

(viii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(ix) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to other entities.

(7) *Procurement documents.* Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component specifies or is issued by the entity subject to the regulations, when applicable, that the provisions of 10 CFR part 21 or 10 CFR 50.55(e) applies, as applicable.

(8) *Coordination with 10 CFR part 21.* The requirements of § 50.55(e) are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under part 21 of this chapter, under § 73.71 of this chapter, or under §§ 50.55(e) or 50.73. For holders of construction permits issued before October 29, 1991, evaluation, reporting and recordkeeping requirements of § 50.55(e) may be met by complying with the comparable requirements of part 21 of this chapter.

(9) *Records retention.* The holder of a construction permit, combined operating license, and manufacturing license must prepare and maintain records necessary to accomplish the purposes of this section, specifically—

(i) Retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the facility or basic component.

(ii) Retain records of evaluations of all deviations and failures to comply under paragraph (e)(3)(i) of this section for the longest of:

(A) Ten (10) years from the date of the evaluation;

(B) Five (5) years from the date that an early site permit is referenced in an application for a combined license; or

(C) Five (5) years from the date of delivery of a manufactured reactor.

(iii) Retain records of all interim reports to the Commission made under paragraph (e)(3)(ii) of this section, or notifications to the Commission made under paragraph (e)(4) of this section for the minimum time periods stated in paragraph (e)(9)(ii) of this section;

(iv) Suppliers of basic components must retain records of:

(A) All notifications sent to affected licensees or purchasers under paragraph (e)(4)(iv) of this section for a minimum of ten (10) years following the date of the notification;

(B) The facilities or other purchasers to whom basic components or associated services were supplied for a minimum of fifteen (15) years from the delivery of the basic component or associated services.

(v) Maintaining records in accordance with this section satisfies the recordkeeping obligations under part 21 of this chapter of the entities, including directors or responsible officers thereof, subject to this section.

* * * * *

(f) * * *

(4) Each holder of an early site permit or a manufacturing license under part 52 of this chapter shall implement the quality assurance program described or referenced in the safety analysis report, including changes to that report. Each holder of a combined license shall implement the quality assurance program for design and construction described or referenced in the safety analysis report, including changes to that report, provided, however, that the holder of a combined license is not subject to the terms and conditions in this paragraph after the Commission makes the finding under § 52.103(g) of this chapter.

(i) Each holder described in paragraph (f)(4) of this section may make a change to a previously accepted quality assurance program description included or referenced in the safety analysis report, if the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the quality assurance program description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(A) Changes to the safety analysis report must be submitted for review as specified in § 50.4. Changes made to NRC-accepted quality assurance topical report descriptions must be submitted as specified in § 50.4.

(B) The submittal of a change to the safety analysis report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of appendix B of this part and the safety analysis report quality assurance program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the changes must be maintained as a facility record for three (3) years.

(D) Changes to the quality assurance program description included or referenced in the safety analysis report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

77. In Section 50.55a, the introductory paragraph, paragraphs (b)(1)(i), (b)(1)(ii), (b)(1)(iii), (b)(1)(v), the introductory text of paragraphs (b)(4) and (d)(1), paragraph (e)(1), the introductory text of paragraph (f)(3), paragraphs (f)(3)(iii), (f)(3)(iv)(B), (f)(4)(i), the introductory text of paragraph (g)(3), paragraphs (g)(4)(i), (g)(4)(v), and (h)(3) are revised to read as follows:

§ 50.55a Codes and standards.

Each construction permit for a utilization facility is subject to the following conditions in addition to those specified in § 50.55. Each combined license for a utilization facility is subject to the following conditions in addition to those specified in § 50.55, except that each combined license for a boiling or pressurized water-cooled nuclear power facility is subject to the conditions in paragraphs (f) and (g) of this section, but only after the Commission makes the finding under § 52.103(g) of this chapter. Each operating license for a boiling or pressurized water-cooled nuclear power facility is subject to the conditions in paragraphs (f) and (g) of this section in addition to those specified in § 50.55. Each manufacturing license, standard design approval, and standard design certification application under part 52 of this chapter is subject to the conditions in paragraphs (a), (b)(1), (b)(4), (c), (d), (e), (f)(3), and (g)(3) of this section.

* * * * *

(b) * * *

(1) * * *

(i) *Section III Materials.* When applying the 1992 Edition of Section III, applicants or licensees must apply the 1992 Edition with the 1992 Addenda of Section II of the ASME Boiler and Pressure Vessel Code.

(ii) *Weld leg dimensions.* When applying the 1989 Addenda through the latest edition, and addenda incorporated by reference in paragraph (b)(1) of this section, applicants or licensees may not apply paragraph NB—3683.4(c)(1), Footnote 11 to Figure NC—3673.2(b)—1, and Figure ND—3673.2(b)—1.

(iii) *Seismic design.* Applicants or licensees may use Articles NB—3200, NB—3600, NC—3600, and ND—3600 up to and including the 1993 Addenda, subject to the limitation specified in paragraph (b)(1)(ii) of this section. Applicants or licensees may not use these articles in the 1994 Addenda through the latest edition and addenda incorporated by reference in paragraph (b)(1) of this section.

* * * * *

(v) *Independence of inspection.* Applicants or licensees may not apply NCA—4134.10(a) of Section III, 1995 Edition, through the latest edition and addenda incorporated by reference in paragraph (b)(1) of this section.

* * * * *

(4) *Design, Fabrication, and Materials Code Cases.* Applicants or licensees may apply the ASME Boiler and Pressure Vessel Code cases listed in NRC Regulatory Guide 1.84, Revision 32, without prior NRC approval subject to the following:

* * * * *

(d)* * *

(1) For a nuclear power plant whose application for a construction permit under this part, or a combined license or manufacturing license under part 52 of this chapter is docketed after May 14, 1984, or for an application for a standard design approval or a standard design

certification docketed after May 14, 1984, components classified Quality Group B 9 must meet the requirements for Class 2 Components in Section III of the ASME Boiler and Pressure Vessel Code.

* * * * *

(e) * * *

(1) For a nuclear power plant whose application for a construction permit under this part, or a combined license or manufacturing license under part 52 of this chapter is docketed after May 14, 1984, or for an application for a standard design approval or a standard design certification docketed after May 14, 1984, components classified Quality Group C 9 must meet the requirements for Class 3 components in Section III of the ASME Boiler and Pressure Vessel Code.

* * * * *

(f) * * *

(3) For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part or design approval, design certification, combined license, or manufacturing license under part 52 of this chapter, was issued on or after July 1, 1974:

(i)-(ii) [Reserved]

(iii)(A) Pumps and valves, in facilities whose construction permit under this part, or design certification or design approval under part 52 of this chapter was issued before November 22, 1999, which are classified as ASME Code Class 1 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in the editions and addenda of Section XI of the ASME Boiler and Pressure Vessel Code incorporated by reference in paragraph (b) of this section (or the optional ASME Code cases that are listed in NRC Regulatory Guide 1.147, through Revision 13, that are incorporated by reference in paragraph (b) of this section) applied

to the construction of the particular pump or valve or the summer 1973 Addenda, whichever is later.

(B) Pumps and valves, in facilities whose construction permit under this part, or design certification, design approval, combined license, or manufacturing license under part 52 of this chapter, is issued on or after November 22, 1999, which are classified as ASME Code Class 1 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in editions and addenda of the ASME OM Code (or the optional ASME Code cases listed in the NRC Regulatory Guide 1.192 that is incorporated by reference in paragraph (b) of this section) referenced in paragraph (b)(3) of this section at the time the construction permit is issued.

(iv)* * *

(B) Pumps and valves, in facilities whose construction permit under this part or design certification or combined license under part 52 of this chapter is issued on or after November 22, 1999, which are classified as ASME Code Class 2 and 3 must be designed and be provided with access to enable the performance of inservice testing of the pumps and valves for assessing operational readiness set forth in editions and addenda of the ASME OM Code (or the optional ASME Code cases listed in the NRC Regulatory Guide 1.192 that is incorporated by reference in paragraph (b) of this section) referenced in paragraph (b)(3) of this section at the time the construction permit is issued.

* * * * *

(4)* * *

(i) Inservice tests to verify operational readiness of pumps and valves, whose function is required for safety, conducted during the initial 120-month interval must comply with the requirements in the latest edition and addenda of the Code incorporated by reference in paragraph (b) of this section on the date 12 months before the date of issuance of the operating

license under this part, or 12 months before the date scheduled for initial loading fuel under a combined license under part 52 of this chapter (or the optional ASME Code cases listed in NRC Regulatory Guide 1.192, that is incorporated by reference in paragraph (b) of this section), subject to the limitations and modifications listed in paragraph (b) of this section.

* * * * *

(g) * * *

(3) For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part, or design certification, design approval, combined license, or manufacturing license under part 52 of this chapter, was issued on or after July 1, 1974:

* * * * *

(4) * * *

(i) Inservice examinations of components and system pressure tests conducted during the initial 120-month inspection interval must comply with the requirements in the latest edition and addenda of the Code incorporated by reference in paragraph (b) of this section on the date 12 months before the date of issuance of the operating license under this part, or 12 months before the date scheduled for initial loading of fuel under a combined license under part 52 of this chapter (or the optional ASME Code cases listed in NRC Regulatory Guide 1.147, through Revision 13, that are incorporated by reference in paragraph (b) of this section), subject to the limitations and modifications listed in paragraph (b) of this section.

* * * * *

(v) For a boiling or pressurized water-cooled nuclear power facility whose construction permit under this part or combined license under part 52 of this chapter was issued after January 1, 1956:

* * * * *

(h) * * *

(3) Safety systems. Applications filed on or after May 13, 1999, for construction permits and operating licenses under this part, and for design approvals, design certifications, and combined licenses under part 52 of this chapter, must meet the requirements for safety systems in IEEE Std. 603—1991 and the correction sheet dated January 30, 1995.

78. In § 50.59, paragraphs (b), (d)(2), and (d)(3) are revised to read as follows:

§ 50.59 Changes, tests, and experiments.

* * * * *

(b) This section applies to each holder of an operating license issued under this part or a combined license issued under part 52 of this chapter, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or § 50.110 or a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility.

* * * * *

(d)* * *

(2) The licensee shall submit, as specified in § 50.4 or § 52.3 of this chapter, as applicable, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For combined licenses, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a combined license to the date the Commission makes its findings under 10 CFR 52.103(g).

(3) The records of changes in the facility must be maintained until the termination of an operating license issued under this part, a combined license issued under part 52 of this chapter, or the termination of a license issued under 10 CFR part 54, whichever is later.

Records of changes in procedures and records of tests and experiments must be maintained for a period of 5 years.

79. In § 50.61, paragraph (b)(1) is revised to read as follows:

§ 50.61 Fracture toughness requirements for protection against pressurized thermal shock events.

* * * * *

(b)* * *

(1) For each pressurized water nuclear power reactor for which an operating license has been issued under this part or a combined license has been issued under part 52 of this chapter, other than a nuclear power reactor facility for which the certifications required under § 50.82(a)(1) have been submitted, the licensee shall have projected values of RT_{PTS} , accepted by the NRC, for each reactor vessel beltline material for the EOL fluence of the material. The assessment of RT_{PTS} must use the calculation procedures given in paragraph (c)(1) of this section, except as provided in paragraphs (c)(2) and (c)(3) of this section. The assessment must specify the bases for the projected value of RT_{PTS} for each vessel beltline material, including the assumptions regarding core loading patterns, and must specify the copper and nickel contents and the fluence value used in the calculation for each beltline material. This assessment must be updated whenever there is a significant² change in projected values of RT_{PTS} , or upon request for a change in the expiration date for operation of the facility.

* * * * *

²Changes to RT_{PTS} values are considered significant if either the previous value or the current value, or both values, exceed the screening criterion before the expiration of the operating license or the combined license under part 52 of this chapter, including any renewed term, if applicable for the plant.

80. In § 50.63, the introductory text of paragraphs (a)(1) and (c)(1) are revised to read as follows:

§ 50.63 Loss of all alternating current power.

(a)* * *

(1) Each light-water-cooled nuclear power plant licensed to operate under this part, each light-water-cooled nuclear power plant licensed under subpart C of 10 CFR part 52 after the Commission makes the finding under § 52.103(g) of this chapter, and each design for a light-water-cooled nuclear power plant approved under a standard design approval, standard design certification, and manufacturing license under part 52 of this chapter must be able to withstand for a specified duration and recover from a station blackout as defined in § 50.2. The specified station blackout duration shall be based on the following factors:

* * * * *

(c)* * *

(1) *Information Submittal.* For each light-water-cooled nuclear power plant licensed to operate on or before *July 21, 1988*, the licensee shall submit the information defined below to the Director of the Office of Nuclear Reactor Regulation by *April 17, 1989*. For each light-water-cooled nuclear power plant licensed to operate after *July 21, 1988*, but before [INSERT EFFECTIVE DATE OF FINAL RULE], the licensee shall submit the information defined below to the Director of the Office of Nuclear Reactor Regulation, by 270 days after the date of license issuance. For each light-water-cooled nuclear power plant operating license application submitted after [INSERT EFFECTIVE DATE OF FINAL RULE], the applicant shall submit the information defined below in its final safety analysis report.

* * * * *

81. In § 50.65, paragraphs (a)(1) and (c) are revised to read as follows:

§ 50.65 Requirements for monitoring the effectiveness of maintenance at nuclear power plants.

* * * * *

(a)(1) Each holder of an operating license for a nuclear power plant under this part and each holder of a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g), shall monitor the performance or condition of structures, systems, or components, against licensee-established goals, in a manner sufficient to provide reasonable assurance that these structures, systems, and components, as defined in paragraph (b) of this section, are capable of fulfilling their intended functions. These goals shall be established commensurate with safety and, where practical, take into account industry-wide operating experience. When the performance or condition of a structure, system, or component does not meet established goals, appropriate corrective action shall be taken. For a nuclear power plant for which the licensee has submitted the certifications specified in § 50.82(a)(1) or 52.110(a)(1) of this chapter, as applicable, this section only shall apply to the extent that the licensee shall monitor the performance or condition of all structures, systems, or components associated with the storage, control, and maintenance of spent fuel in a safe condition, in a manner sufficient to provide reasonable assurance that these structures, systems, and components are capable of fulfilling their intended functions.

* * * * *

(c) The requirements of this section shall be implemented by each licensee no later than July 10, 1996. For combined licenses under part 52, the requirements of this section shall be implemented by the licensee no later than 30 days before the scheduled date for initial loading of fuel.

82. In § 50.70 paragraphs (a) and (b)(2) are revised to read as follows:

§ 50.70 Inspections.

(a) Each applicant for or holder of a license, including a construction permit or an early site permit, shall permit inspection, by duly authorized representatives of the Commission, of his records, premises, activities, and of licensed materials in possession or use, related to the license or construction permit or early site permit as may be necessary to effectuate the purposes of the Act, as amended, including section 105 of the Act, and the Energy Reorganization Act of 1974, as amended.

(b)* * *

(2) For a site with a single power reactor or fuel facility licensed under part 50 or part 52 of this chapter, or a facility issued a manufacturing license under part 52, the space provided shall be adequate to accommodate a full-time inspector, a part-time secretary and transient NRC personnel and will be generally commensurate with other office facilities at the site. A space of 250 square feet either within the site's office complex or in an office trailer or other onsite space is suggested as a guide. For sites containing multiple power reactor units or fuel facilities, additional space may be requested to accommodate additional full-time inspector(s). The office space that is provided shall be subject to the approval of the Director, Office of Nuclear Reactor Regulation. All furniture, supplies and communication equipment will be furnished by the Commission.

* * * * *

83. In § 50.71, paragraphs (a), (c), (d)(1), and the introductory text of paragraph (e) are revised, paragraph (f) is redesignated as paragraph (g) and revised, and new paragraph (f) is added to read as follows:

§ 50.71 Maintenance of records, making of reports.

(a) Each licensee, including each holder of a construction permit or early site permit, shall maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations, and orders of the Commission in effectuating the purposes of the Act, including Section 105 of the Act, and the Energy Reorganization Act of 1974, as amended. Reports must be submitted in accordance with § 50.4 or 10 CFR 52.3, as applicable.

* * * * *

(c) Records that are required by the regulations in this part or part 52 of this chapter by license condition or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license or, in the case of an early site permit, until the permit expires.

(d)(1) Records which must be maintained under this part or part 52 of this chapter may be the original or a reproduced copy or microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with, and loss of records.

* * * * *

(e) Each person licensed to operate a nuclear power reactor under the provisions of § 50.21 or § 50.22 shall update periodically, as provided in paragraphs (e) (3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the license, to assure that the information included in the report contains the latest information

developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the original FSAR, or as appropriate, the last update to the FSAR under this section. The submittal shall include the effects¹ of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) or, in the case of a license that references a certified design, in accordance with § 52.98(c); and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

* * * * *

(f) Each person licensed to manufacture a nuclear power reactor under subpart F of 10 CFR part 52 shall update the FSAR originally submitted as part of the application to reflect any modification to the design that is approved by the Commission under § 52.171 of this chapter, and any new analyses of the design performed by or on behalf of the licensee at the NRC's request. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee with respect to the modification approved under § 52.171 of this chapter or the analyses requested by the Commission under § 52.171 of this chapter. The updated information shall be appropriately located within the update to the FSAR.

(g) The provisions of this section apply to nuclear power reactor licensees that have submitted the certification of permanent cessation of operations required under §§ 50.82(a)(1)(i)

¹Effects of changes includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

or 52.110(a)(1) of this chapter. The provisions of paragraphs (a), (c), and (d) of this section also apply to non-power reactor licensees that are no longer authorized to operate.

84. In § 50.73, paragraph (a)(1) is revised to read as follows:

§ 50.73 Licensee event report system.

(a) * * *

(1) The holder of an operating license under this part or a combined license under part 52 of this chapter (after the Commission has made the finding under § 52.103(g) of this chapter) for a nuclear power plant (licensee) shall submit a Licensee Event Report (LER) for any event of the type described in this paragraph within 60 days after the discovery of the event. In the case of an invalid actuation reported under §50.73(a)(2)(iv), other than actuation of the reactor protection system (RPS) when the reactor is critical, the licensee may, at its option, provide a telephone notification to the NRC Operations Center within 60 days after discovery of the event instead of submitting a written LER. Unless otherwise specified in this section, the licensee shall report an event if it occurred within 3 years of the date of discovery regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

* * * * *

85. In § 50.75, paragraphs (a) and (b) are revised, paragraphs (f)(1), (f)(2), (f)(3), and (f)(4) are redesignated as paragraphs (f)(2), (f)(3), (f)(4), and (f)(5), respectively, and paragraphs (e)(3) and (f)(1) are added to read as follows:

§ 50.75 Reporting and recordkeeping for decommissioning planning.

(a) This section establishes requirements for indicating to NRC how a licensee will provide reasonable assurance that funds will be available for the decommissioning process.

For power reactor licensees (except a holder of a manufacturing license under part 52 of this chapter), reasonable assurance consists of a series of steps as provided in paragraphs (b), (c), (e), and (f) of this section. Funding for the decommissioning of power reactors may also be subject to the regulation of Federal or State Government agencies (e.g., Federal Energy Regulatory Commission (FERC) and State Public Utility Commissions) that have jurisdiction over rate regulation. The requirements of this section, in particular paragraph (c) of this section, are in addition to, and not substitution for, other requirements, and are not intended to be used by themselves or by other agencies to establish rates.

(b) Each power reactor applicant for or holder of an operating license, and each applicant for a combined license under subpart C of 10 CFR part 52 for a production or utilization facility of the type and power level specified in paragraph (c) of this section shall submit a decommissioning report, as required by § 50.33(k).

(1) For an applicant for or holder of an operating license under part 50, the report must contain a certification that financial assurance for decommissioning will be (for a license applicant), or has been (for a license holder), provided in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section. For an applicant for a combined license under subpart C of 10 CFR part 52, the report must contain a certification that financial assurance for decommissioning will be provided no later than 30 days after the Commission publishes notice in the *Federal Register* under § 52.103(a) in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section, adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section.

(2) The amount to be provided must be adjusted annually using a rate at least equal to that stated in paragraph (c)(2) of this section.

(3) The amount must use one or more of the methods described in paragraph (e) of this section as acceptable to the NRC.

(4) The amount stated in the applicant's or licensee's certification may be based on a cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC; provided, however, that an applicant for or holder of a combined license need not obtain such financial instrument or submit a copy to the Commission except as provided in paragraph (e)(3) of this section.

* * * * *

(e) * * *

* * * * *

(3) Each holder of a combined license under subpart C of 10 CFR part 52 shall, following issuance of the combined license until the date that the Commission makes the finding under 10 CFR 52.103(g), submit a report to the NRC, by March 31 of each year, containing an update to the certification described under paragraph (b)(1) of this section. No later than 30 days after the Commission publishes notice in the *Federal Register* under 10 CFR 52.103(a), the licensee shall submit a report containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification; and a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.

(f)(1) Each power reactor licensee shall report, on a calendar-year basis, to the NRC by March 31, 1999, and at least once every 2 years on the status of its decommissioning funding for each reactor or part of a reactor that it owns. However, each holder of a combined license under part 52 of this chapter need not begin reporting until the date that the Commission has

made the finding under § 52.103(g) of this chapter. The information in this report must include, at a minimum the amount of decommissioning funds estimated to be required under 10 CFR 50.75(b) and (c); the amount accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying under paragraph (e)(1)(v) of this section; any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and any material changes to trust agreements. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed so that it will close within 5 years (before the end of its licensed life), or has already closed (before the end of its licensed life), or for plants involved in mergers or acquisitions shall submit this report annually.

* * * * *

86. Section 50.78 is revised to read as follows:

§ 50.78 Installation information and verification.

Each holder of a construction permit and each holder of a combined license shall, if requested by the Commission, submit installation information on Form-71, permit verification thereof by the International Atomic Energy Agency, and take other action as may be necessary to implement the US/IAEA Safeguards Agreement, in the manner set forth in § 75.6 and §§ 75.11 through 75.14 of this chapter.

87. In § 50.80, paragraph (a) is revised to read as follows:

§ 50.80 Transfer of licenses.

(a) No license for a production or utilization facility (including, but not limited to, permits under this part and part 52 of this chapter, and licenses under parts 50 and 52 of this chapter), or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.

* * * * *

88. In § 50.81, paragraph (d)(1) is revised, and a new paragraph (d)(3) is added to read as follows:

§ 50.81 Creditor regulations.

(d)* * *

(1) *License* includes any license under this chapter, any construction permit under this part, and any early site permit under part 52 of this chapter, which may be issued by the Commission with regard to a facility;

* * * * *

(3) *Facility* includes but is not limited to, a site which is the subject of an early site permit under subpart A of part 52 of this chapter, and a reactor manufactured under a manufacturing license under subpart F of part 52.

89. Section 50.90 is revised to read as follows:

§ 50.90 Application for amendment of license or construction permit.

Whenever a holder of a license, including a construction permit and operating license under this part, and a combined license, and manufacturing license under part 52 of this chapter, desires to amend the license or permit, application for an amendment must be filed with the Commission, as specified in § 50.4 or § 52.3 of this chapter, as applicable, fully

describing the changes desired, and following as far as applicable, the form prescribed for original applications.

90. In § 50.91, the introductory text is revised to read as follows:

§ 50.91 Notice for public comment; State consultation.

The Commission will use the following procedures for an application requesting an amendment to an operating license under this part or a combined licensed under part 52 of this chapter for a facility licensed under §§ 50.21(b) or 50.22, or for a testing facility, except for amendments subject to hearings governed by 10 CFR part 2, subpart L. For amendments subject to 10 CFR part 2, subpart L, the following procedures will apply only to the extent specifically referenced in § 2.309(b) of this chapter, except that notice of opportunity for hearing must be published in the *Federal Register* at least 30 days before the requested amendment is issued by the Commission:

* * * * *

91. Section 50.92 paragraph (a), and the introductory text of paragraph (c) are revised to read as follows:

§ 50.92 Issuance of amendment.

(a) In determining whether an amendment to a license or construction permit will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses or construction permits to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a construction permit will be issued before the issuance of the amendment to the license, provided however, that If the application involves a material alteration to a nuclear power reactor manufactured under part 52 of this chapter before its installation at a site, or a combined license before the date that the

Commission makes the finding under § 52.103(g) of this chapter, no application for a construction permit is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action:

- (1) Under § 2.105 of this chapter before acting thereon; and
- (2) As soon as practicable after the application has been docketed.

* * * * *

(c) The Commission may make a final determination, under the procedures in § 50.91, that a proposed amendment to an operating license, combined license or manufacturing license for a facility or reactor licensed under § 50.21(b) or § 50.22, or for a testing facility involves no significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:

* * * * *

92. Section 50.100 is revised to read as follows:

§ 50.100 Revocation, suspension, modification of licenses, permits, and approvals for cause.

A license, permit, or standard design approval under part 52 of this chapter may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license, permit, or approval on an original application (other than those relating to §§ 50.51, 50.42(a), and 50.43(b)); or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the permit or license, *provided* that failure to make timely completion of the proposed construction or alteration of a facility under a construction permit

shall be governed by the provisions of § 50.55(b); or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, permit, approval, or order of the Commission.

93. In § 50.109, paragraph (a)(1) is revised to read as follows:

§ 50.109 Backfitting.

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after:

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985;

(ii) Six (6) months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985;

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses;

(iv) The date of issuance of the design approval under subpart E of part 52 of this chapter;

(v) The date of issuance of a manufacturing license under subpart F of part 52 of this chapter;

(vi) The date of issuance of the first construction permit issued for a duplicate design under appendix N of this part; or

(vii) The date of issuance of a combined license under subpart C of part 52 of this chapter, provided that if the combined license references an early site permit, the provisions in § 52.39 of this chapter apply with respect to the site characteristics, design parameters, and terms and conditions specified in the early site permit. If the combined license references a standard design certification rule under subpart B of 10 CFR part 52, the provisions in § 52.63 of this chapter apply with respect to the design matters resolved in the standard design certification rule, *provided however*, that if any specific backfitting limitations are included in a referenced design certification rule, those limitations shall govern. If the combined license references a standard design approval under subpart E of 10 CFR part 52, the provisions in § 52.145 of this chapter apply with respect to the design matters resolved in the standard design approval. If the combined license uses a reactor manufactured under a manufacturing license under subpart F of 10 CFR part 52, the provisions of § 52.171 of this chapter apply with respect to matters resolved in the manufacturing license proceeding.

* * * * *

94. Section 50.120 is revised to read as follows:

§ 50.120 Training and qualification of nuclear power plant personnel.

(a) *Applicability.* The requirements of this section apply to each applicant for and each holder of an operating license issued under this part and each holder of a combined license issued under part 52 of this chapter for a nuclear power plant of the type specified in § 50.21(b) or § 50.22.

(b) *Requirements.* (1)(i) Each nuclear power plant operating license applicant, by 18 months prior to fuel load, and each holder of an operating license shall establish, implement, and maintain a training program that meets the requirements of paragraphs (b)(2) and (b)(3) of this section.

(ii) Each holder of a combined license shall establish, implement, and maintain the training program that meets the requirements of paragraphs (b)(2) and (b)(3) of this section, as described in the final safety analysis report no later than 18 months before the scheduled date for initial loading of fuel.

(2) The training program must be derived from a systems approach to training as defined in 10 CFR 55.4, and must provide for the training and qualification of the following categories of nuclear power plant personnel:

- (i) Non-licensed operator.
- (ii) Shift supervisor.
- (iii) Shift technical advisor.
- (iv) Instrument and control technician.
- (v) Electrical maintenance personnel.
- (vi) Mechanical maintenance personnel.
- (vii) Radiological protection technician.
- (viii) Chemistry technician.
- (ix) Engineering support personnel.

(3) The training program must incorporate the instructional requirements necessary to provide qualified personnel to operate and maintain the facility in a safe manner in all modes of operation. The training program must be developed to be in compliance with the facility license, including all technical specifications and applicable regulations. The training program must be periodically evaluated and revised as appropriate to reflect industry experience as well as changes to the facility, procedures, regulations, and quality assurance requirements. The training program must be periodically reviewed by licensee management for effectiveness. Sufficient records must be maintained by the licensee to maintain program integrity and kept available for NRC inspection to verify the adequacy of the program.

95. In Appendix A to Part 50, the first paragraph under the introduction and the second paragraph under Criterion 19 are revised to read as follows:

APPENDIX A TO PART 50 - GENERAL DESIGN CRITERIA FOR NUCLEAR POWER PLANTS

* * * * *

Introduction

Under the provisions of § 50.34, an application for a construction permit must include the principal design criteria for a proposed facility. Under the provisions of 10 CFR 52.47, 52.79, 52.137, and 52.157, an application for a design certification, combined license, design approval, or manufacturing license, respectively, must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.

* * * * *

Criterion 19 - Control Room.

* * * * *

Applicants for and holders of construction permits and operating licenses under this part who apply on or after January 10, 1997, applicants for design approvals or certifications under part 52 of this chapter who apply on or after January 10, 1997, applicants for and holders of combined licenses or manufacturing licenses under part 52 of this chapter who do not reference a standard design approval or certification, or holders of operating licenses using an alternative source term under § 50.67, shall meet the requirements of this criterion, except that with regard to control room access and occupancy, adequate radiation protection shall be provided to

ensure that radiation exposures shall not exceed 0.05 Sv (5 rem) total effective dose equivalent (TEDE) as defined in § 50.2 for the duration of the accident.

* * * * *

96. In Appendix B to Part 50, the Introduction and Section I are revised to read as follows:

Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for a combined license under part 52 of this chapter is required by the provisions of § 52.79 of this chapter to include in its final safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation. For applications submitted after [INSERT DATE OF FINAL RULE], every applicant for an early site permit under part 52 of this chapter is required by the provisions of § 52.17 to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval, design certification, or manufacturing license under part 52 of this chapter is required by the provisions of 10 CFR 52.137, 52.47, and 52.157, respectively, to include in its final safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the

facility. Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this appendix, “quality assurance” comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

I. Organization

The applicant¹ shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and

¹While the term “applicant” is used in these criteria, the requirements are, of course, applicable after such a person has received a license to construct and operate a nuclear power plant or a fuel reprocessing plant or has received an early site permit, design approval, design certification, or manufacturing license, as applicable. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits, operating licenses, early site permits, design approvals, combined licenses, and manufacturing licenses.

duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. These persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being performed, shall have direct access to the levels of management necessary to perform this function.

* * * * *

97. In Appendix C to Part 50, the heading, the first paragraph of General Information, and the headings of Sections I.A and II.A, and Section III are revised to read as follows:

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

General Information

This appendix is intended to apprise applicants for construction permits and combined licenses for production or utilization facilities of the types described in § 50.21(b) or § 50.22, or testing facilities, of the general kinds of financial data and other related information that will demonstrate the financial qualification of the applicant to carry out the activities for which the permit or license is sought. The kind and depth of information described in this guide is not intended to be a rigid and absolute requirement. In some instances, additional pertinent material may be needed. In any case, the applicant should include information other than that specified, if the information is pertinent to establishing the applicant's financial ability to carry out the activities for which the permit or license is sought.

* * * * *

I. * * *

A. Applications for construction permits or combined licenses

* * * * *

II. * * *

A. Applications for construction permits or combined licenses

* * * * *

III. ANNUAL FINANCIAL STATEMENT

Each holder of a construction permit for a production or utilization facility of a type described in § 50.21(b) or § 50.22 or a testing facility, and each holder of a combined license issued under part 52 of this chapter, is required by § 50.71(b) to file its annual financial report

with the Commission at the time of issuance. This requirement does not apply to licensees or holders of construction permits for medical and research reactors.

* * * * *

98. In Appendix E to Part 50, Sections I, III, IV.F.2.a, IV.F.2.c, and V are revised, and footnotes 6, 7, 8, 9, and 10 are redesignated as 7, 8, 9, 10, and 11, respectively, and a new footnote 6 is added to read as follows:

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

I. Introduction

Each applicant for a construction permit is required by § 50.34(a) to include in the preliminary safety analysis report a discussion of preliminary plans for coping with emergencies. Each applicant for an operating license is required by § 50.34(b) to include in the final safety analysis report plans for coping with emergencies. Each applicant for a combined license under subpart C of part 52 of this chapter is required by § 52.79 of this chapter to include in the application plans for coping with emergencies. Each applicant for an early site permit under subpart A of part 52 of this chapter may submit plans for coping with emergencies under § 52.17 of this chapter.

* * * * *

III. The Final Safety Analysis Report or Early Site Permit Application

The final safety analysis report shall contain the plans for coping with emergencies. Early site permit applications may contain plans for coping with emergencies under § 52.17(b) of this chapter. The plans shall be an expression of the overall concept of operation; they shall describe the essential elements of advance planning that have been considered and the

provisions that have been made to cope with emergency situations. The plans shall incorporate information about the emergency response roles of supporting organizations and offsite agencies. That information shall be sufficient to provide assurance of coordination among the supporting groups and with the licensee.

The plans submitted must include a description of the elements set out in Section IV for the emergency planning zones (EPZs) to an extent sufficient to demonstrate that the plans provide reasonable assurance that adequate protective measures can and will be taken in the event of an emergency.

IV. Content of Emergency Plans

* * * * *

F.* * *

2.* * *

a. A full participation⁴ exercise which tests as much of the licensee, State, and local emergency plans as is reasonably achievable without mandatory public participation shall be conducted for each site at which a power reactor is located.

(i) For an operating license issued under this part, this exercise must be conducted within two years before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated power) of the first reactor and shall include participation by each State and local government within the plume exposure pathway EPZ and each state within the ingestion exposure pathway EPZ. If the full participation exercise is conducted more than

⁴*Full participation* when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite local and State authorities and licensee personnel physically and actively take part in testing their integrated capability to adequately assess and respond to an accident at a commercial nuclear power plant. *Full participation* includes testing major observable portions of the onsite and offsite emergency plans and mobilization of State, local and licensee personnel and other resources in sufficient numbers to verify the capability to respond to the accident scenario.

one year prior to issuance of an operating licensee for full power, an exercise which tests the licensee's onsite emergency plans must be conducted within one year before issuance of an operating license for full power. This exercise need not have State or local government participation.

(ii) For a combined license issued under part 52 of this chapter, this exercise must be conducted within two years of the scheduled date for initial loading of fuel. If the first full participation exercise is conducted more than one year before the scheduled date for initial loading of fuel, an exercise which tests the licensee's onsite emergency plans must be conducted within one year before the scheduled date for initial loading of fuel. This exercise need not have State or local government participation. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of the first full participation exercise, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

(iii) For a combined licensee issued under part 52 of this chapter, if the applicant currently has an operating reactor at the site, an exercise, either full or partial participation,⁵ shall be conducted for each subsequent reactor constructed on the site. This exercise may be incorporated in the exercise requirements of paragraphs (2)(b) and (2)(c) of this section. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of this exercise for the new reactor, or if the Commission finds that the state of emergency

⁵ *Partial participation* when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite authorities shall actively take part in the exercise sufficient to test direction and control functions; i.e., (a) protective action decision making related to emergency action levels, and (b) communication capabilities among affected State and local authorities and the licensee.

preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

* * * * *

c. Offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the radiological response plan. Where the offsite authority has a role under a radiological response plan for more than one site, it shall fully participate in one exercise every two years and shall, at least, partially participate in other offsite plan exercises in this period. If two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the elements defining co-located licensees,⁶ each licensee shall:

- (1) Conduct an exercise biennially of its onsite emergency plan; and
- (2) Participate quadrennially in an offsite biennial full or partial participation exercise;

and

(3) Conduct emergency preparedness activities and interactions in the years between its participation in the offsite full or partial participation exercise with offsite authorities, to test and maintain interface among the affected State and local authorities and the licensee. Co-located licensees shall also participate in emergency preparedness activities and interaction with offsite authorities for the period between exercises.

* * * * *

V. Implementing Procedures

⁶ Co-located licensees are two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the following emergency planning and siting elements:

- a. plume exposure and ingestion emergency planning zones;
- b. offsite governmental authorities;
- c. offsite emergency response organizations;
- d. public notification system; and/or
- e. emergency facilities.

No less than 180 days before the scheduled issuance of an operating license for a nuclear power reactor or a license to possess nuclear material or the date that the Commission makes the finding under § 52.103 of this chapter, the applicant's or licensee's detailed implementing procedures for its emergency plan shall be submitted to the Commission as specified in § 50.4. Licensees who are authorized to operate a nuclear power facility shall submit any changes to the emergency plan or procedures to the Commission, as specified in § 50.4, within 30 days of such changes.

* * * * *

99. In Appendix I to Part 50, the first paragraphs of Sections I, II, IV, V, and the introductory paragraph of Sections A.3 of the Concluding Statement of Position of the Regulatory Staff (Docket–RM–50–2) are revised to read as follows:

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

SECTION I. *Introduction.* Section 50.34a provides that an application for a construction permit shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal conditions, including expected occurrences. In the case of an application filed on or after January 2, 1971, the application must also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as practicable. Sections 52.47, 52.79, 52.137, and 52.157 of this chapter provide that applications for design certification, combined license, design approval, or manufacturing license, respectively, shall include a description of the equipment and procedures for the control

of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems.

* * * * *

SECTION II. *Guides on design objectives for light-water-cooled nuclear power reactors licensed under 10 CFR part 50 or part 52* of this chapter. The guides on design objectives set forth in this section may be used by an applicant for a construction permit as guidance in meeting the requirements of §50.34a(a), or by an applicant for a combined license under part 52 of this chapter as guidance in meeting the requirements of § 50.34a(d), or by an applicant for a design approval, a design certification, or a manufacturing license as guidance in meeting the requirements of § 50.34a(e). The applicant shall provide reasonable assurance that the following design objectives will be met.

* * * * *

SECTION IV. *Guides on technical specifications for limiting conditions for operation for light-water-cooled nuclear power reactors licensed under 10 CFR part 50 or part 52* of this chapter. The guides on limiting conditions for operation for light-water-cooled nuclear power reactors set forth below may be used by an applicant for an operating license under this part or a design certification or combined license under part 52 of this chapter, or a licensee who has submitted a certification of permanent cessation of operations under § 50.82(a)(1) or § 52.110 of this chapter as guidance in developing technical specifications under § 50.36a(a) to keep levels of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable.

* * * * *

SECTION V. *Effective dates.* A. The guides for limiting conditions for operation set forth in this appendix shall be applicable in any case in which an application was filed on or after

January 2, 1971, for construction permit under this part or a design certification, a combined license, or a manufacturing license under part 52 of this chapter.

* * * * *

CONCLUDING STATEMENT OF POSITION OF THE REGULATORY STAFF

(DOCKET-RM-50-2)

GUIDES ON DESIGN OBJECTIVES FOR LIGHT-WATER-COOLED
NUCLEAR POWER REACTORS

A. * * *

3. Notwithstanding the guidance in paragraph A.2, for a particular site, if an applicant for a construction permit under this part or a design approval, a design certification, a combined license, or a manufacturing license under part 52 of this chapter has proposed baseline in-plant control measures² to reduce the possible sources of radioactive material in liquid effluent releases and the calculated quantity exceeds the quantity set forth in paragraph A.2, the requirements for design objectives for radioactive material in liquid effluents may be deemed to have been met provided:

* * * * *

²These measures may include treatment of clear liquid waste streams (normally tritiated, nonaerated, low conductivity equipment drains and pump seal leakoff), dirty liquid waste streams (normally nontritiated, aerated, high conductivity building sumps, floor and sample station drains), steam generator blowdown streams, chemical waste streams, low purity and high purity liquid streams (resin regenerate and laboratory wastes), as appropriate for the type of reactor.

100. In Appendix J to Part 50 in Option A, Section I, and paragraph II.k are revised and in Option B, Section I, and paragraphs V.B.2 and 3 are revised to read as follows:

**APPENDIX J TO PART 50—PRIMARY REACTOR CONTAINMENT LEAKAGE TESTING
FOR WATER-COOLED REACTORS**

* * * * *

OPTION A—PRESCRIPTIVE REQUIREMENTS

* * * * *

I. Introduction

One of the conditions of all operating licenses under this part and combined licenses under part 52 of this chapter for water-cooled power reactors as specified in §50.54(o) is that primary reactor containments shall meet the containment leakage test requirements set forth in this appendix. These test requirements provide for preoperational and periodic verification by tests of the leak-tight integrity of the primary reactor containment, and systems and components which penetrate containment of water-cooled power reactors, and establish the acceptance criteria for these tests. The purposes of the tests are to assure that (a) leakage through the primary reactor containment and systems and components penetrating primary containment shall not exceed allowable leakage rate values as specified in the technical specifications or associated bases; and (b) periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment. These test requirements may also be used for guidance in establishing appropriate containment leakage test requirements in technical specifications or associated bases for other types of nuclear power reactors.

II.* * *

K. La (percent/24 hours) means the maximum allowable leakage rate at pressure Pa as specified for preoperational tests in the technical specifications or associated bases, and as specified for periodic tests in the operating license or combined license, including the technical specifications in any referenced design certification or manufactured reactor used at the facility.

* * * * *

OPTION B—PERFORMANCE-BASED REQUIREMENTS

* * * * *

I. Introduction

One of the conditions required of all operating licenses and combined licenses for light-water-cooled power reactors as specified in §50.54(o) is that primary reactor containments meet the leakage-rate test requirements in either Option A or B of this appendix. These test requirements ensure that (a) leakage through these containments or systems and components penetrating these containments does not exceed allowable leakage rates specified in the technical specifications; and (b) integrity of the containment structure is maintained during its service life. Option B of this appendix identifies the performance-based requirements and criteria for preoperational and subsequent periodic leakage-rate testing.³

* * * * *

V.* * *

B.* * *

2. A licensee or applicant for an operating license under this part or a combined license under part 52 of this chapter may adopt Option B, or parts thereof, as specified in Section V.A of this appendix, by submitting its implementation plan and request for revision to technical

³Specific guidance concerning a performance-based leakage-test program, acceptable leakage-rate test methods, procedures, and analyses that may be used to implement these requirements and criteria are provided in Regulatory Guide 1.163, "Performance-Based Containment Leak-Test Program."

specifications (see paragraph B.3 of this section) to the Director of the Office of Nuclear Reactor Regulation.

3. The regulatory guide or other implementation document used by a licensee or applicant for an operating license under this part or a combined license under part 52 of this chapter to develop a performance-based leakage-testing program must be included, by general reference, in the plant technical specifications. The submittal for technical specification revisions must contain justification, including supporting analyses, if the licensee chooses to deviate from methods approved by the Commission and endorsed in a regulatory guide.

* * * * *

101. Appendix M to Part 50 is removed.

Appendix M to Part 50 [Removed and reserved]

102. Appendix O to Part 50 is removed.

Appendix O to Part 50 [Removed and reserved]

103. In Appendix S to Part 50, the first paragraph titled “General Information,” Section I(a), and Section III are revised to read as follows:

Appendix S to Part 50—Earthquake Engineering Criteria for Nuclear Power Plants

General Information

This appendix applies to applicants for a construction permit or operating license under part 50, or a design certification, combined license, design approval, or manufacturing license under part 52 of this chapter, on or after January 10, 1997. However, for either an operating license applicant or holder whose construction permit was issued before January 10, 1997, the earthquake engineering criteria in Section VI of appendix A to 10 CFR part 100 continues to

apply. Paragraphs IV.a.1.i, IV.a.1.ii, IV.4.b, and IV.4.c of this appendix apply to applicants for an early site permit under part 52.

I. Introduction

(a) Each applicant for a construction permit, operating license, design certification, combined license, design approval, or manufacturing license is required by §§ 50.34(a)(12), 50.34(b)(10), or 10 CFR 52.47, 52.79, 52.137, or 52.157, and General Design Criterion 2 of appendix A to this part, to design nuclear power plant structures, systems, and components important to safety to withstand the effects of natural phenomena, such as earthquakes, without loss of capability to perform their safety functions. Also, as specified in § 50.54(ff), nuclear power plants that have implemented the earthquake engineering criteria described herein must shut down if the criteria in paragraph IV(a)(3) of this appendix are exceeded.

* * * * *

III. Definitions

As used in these criteria:

Combined license means a combined construction permit and operating license with conditions for a nuclear power facility issued under subpart C of part 52 of this chapter.

Design Approval means an NRC staff approval, issued under subpart E of part 52 of this chapter, of a final standard design for a nuclear power reactor of the type described in 10 CFR 50.22.

Design Certification means a Commission approval, issued under subpart B of part 52 of this chapter, of a standard design for a nuclear power facility.

Manufacturing license means a license, issued under subpart F of part 52 of this chapter, authorizing the manufacture of nuclear power reactors but not their installation into facilities located at the sites on which the facilities are to be operated.

Operating basis earthquake ground motion (OBE) is the vibratory ground motion for which those features of the nuclear power plant necessary for continued operation without undue risk to the health and safety of the public will remain functional. The operating basis earthquake ground motion is only associated with plant shutdown and inspection unless specifically selected by the applicant as a design input.

Response spectrum is a plot of the maximum responses (acceleration, velocity, or displacement) of idealized single-degree-of-freedom oscillators as a function of the natural frequencies of the oscillators for a given damping value. The response spectrum is calculated for a specified vibratory motion input at the oscillators' supports.

Safe-shutdown earthquake ground motion (SSE) is the vibratory ground motion for which certain structures, systems, and components must be designed to remain functional.

Structures, systems, and components required to withstand the effects of the safe-shutdown earthquake ground motion or surface deformation are those necessary to assure:

- (1) The integrity of the reactor coolant pressure boundary;
- (2) The capability to shut down the reactor and maintain it in a safe-shutdown condition;

or

- (3) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guideline exposures of § 50.34(a)(1).

Surface deformation is distortion of geologic strata at or near the ground surface by the processes of folding or faulting as a result of various earth forces. Tectonic surface deformation is associated with earthquake processes.

* * * * *

**PART 51 - ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING
AND RELATED REGULATORY FUNCTIONS**

104. The authority citation for Part 51 continues to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2201, 2297f); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853-854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95-604, Title II, 92 Stat. 3033-3041; and sec. 193, Pub. L. 101-575, 104 Stat. 2835 (42 U.S.C. 2243). Sections 51.20, 51.30, 51.60, 51.80, and 51.97 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241, and sec. 148, Pub. L. 100-203, 101 Stat. 1330-223 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036-3038 (42 U.S.C. 2021) and under Nuclear Waste Policy Act of 1982, sec. 121, 96 Stat. 2228 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act of 1982, sec. 114(f), 96 Stat. 2216, as amended (42 U.S.C. 10134(f)).

105. In § 51.17, paragraph (b) is revised to read as follows:

§ 51.17 Information collection requirements; OMB approval.

* * * * *

(b) The approved information collection requirements in this part appear in §§ 51.6, 51.16, 51.41, 51.45, 51.50, 51.51, 51.52, 51.53, 51.54, 51.58, 51.60, 51.61, 51.62, 51.66, 51.68, and 51.69.

106. In § 51.20, paragraph (b)(6) is removed and reserved, and paragraphs (b)(1) and (b)(2) are revised to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b)* * *

(1) Issuance of a limited work authorization or a permit to construct a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 of this chapter, or issuance of an early site permit under part 52 of this chapter.

(2) Issuance or renewal of a full power or design capacity license to operate a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 of this chapter, or a combined license under part 52 of this chapter.

* * * * *

(6) **[Reserved]**

* * * * *

107. In § 51.22, paragraphs (c)(3)(i), (c)(9), the introductory text of paragraphs (c)(10) and (c)(12), and paragraph (c)(17) are revised, and paragraphs (c)(22) and (c)(23) are added to read as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c)* * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 39, 40, 50, 51, 52, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to-

(i) Procedures for filing and reviewing applications for licenses or construction permits or early site permits or other forms of permission or for amendments to or renewals of licenses or construction permits or early site permits or other forms of permission;

* * * * *

(9) Issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter, which changes a requirement with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter, or which changes an inspection or a surveillance requirement, provided that- -

(i) The amendment involves no significant hazards consideration;

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and

(iii) There is no significant increase in individual or cumulative occupational radiation exposure.

(10) Issuance of an amendment to a permit or license under parts 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 52, 60, 61, 63, 70, or part 72 of this chapter which—

* * * * *

(12) Issuance of an amendment to a license under parts 50, 52, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted under parts 50, 52, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

* * * * *

(17) Issuance of an amendment to a permit or license under parts 30, 40, 50, 52, or part 70 of this chapter which deletes any limiting condition of operation or monitoring requirement

based on or applicable to any matter subject to the provisions of the Federal Water Pollution Control Act.

* * * * *

(22) Issuance of a standard design approval under part 52 of this chapter.

(23) The Commission finding for a combined license under § 52.103(g) of this chapter.

* * * * *

108. In § 51.23 paragraphs (b) and (c) are revised to read as follows:

§ 51.23 Temporary storage of spent fuel after cessation of reactor operation—generic determination of no significant environmental impact.

* * * * *

(b) Accordingly, as provided in §§ 51.30(b), 51.53, 51.61, 51.80(b), 51.95 and 51.97(a), and within the scope of the generic determination in paragraph (a) of this section, no discussion of any environmental impact of spent fuel storage in reactor facility storage pools or independent spent fuel storage installations (ISFSI) for the period following the term of the reactor operating license or amendment, reactor combined license or amendment, or initial ISFSI license or amendment for which application is made, is required in any environmental report, environmental impact statement, environmental assessment or other analysis prepared in connection with the issuance or amendment of an operating license for a nuclear power reactor under parts 50 and 54 of this chapter, or issuance or amendment of a combined license for a nuclear power reactor under parts 52 and 54 of this chapter, or the issuance of an initial license for storage of spent fuel at an ISFSI, or any amendment thereto.

(c) This section does not alter any requirements to consider the environmental impacts of spent fuel storage during the term of a reactor operating license or combined license, or a license for an ISFSI in a licensing proceeding.

109. In § 51.30, paragraph (a) is revised, and paragraphs (d) and (e) are added to read as follows:

§ 51.30 Environmental assessment.

(a) An environmental assessment for proposed actions, other than those for a standard design certification or a manufacturing license under part 52 of this chapter, shall identify the proposed action and include:

(1) A brief discussion of:

(i) The need for the proposed action;

(ii) Alternatives as required by section 102(2)(E) of NEPA;

(iii) The environmental impacts of the proposed action and alternatives as appropriate;

and

(2) A list of agencies and persons consulted, and identification of sources used.

* * * * *

(d) An environmental assessment for a standard design certification under subpart B of part 52 of this chapter must identify the proposed action, and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives (SAMDA) and the bases for not incorporating SAMDA in the design certification. An environmental assessment for an amendment to a design certification will be limited to the consideration of whether the design change which is the subject of the proposed amendment renders a SAMDA previously rejected in the earlier environmental assessment to become cost beneficial, or results in the identification of new SAMDA, in which case the costs and benefits of new SAMDA and the bases for not incorporating new SAMDA in the design certification must be addressed.

(e) An environmental assessment for a manufacturing license under subpart F of part 52 of this chapter must identify the proposed action, and will be limited to the consideration of the costs and benefits of SAMDA and the bases for not incorporating SAMDA in the

manufacturing license. An environmental assessment for an amendment to a manufacturing license will be limited to consideration whether the design change which is the subject of the proposed amendment either renders a SAMDA previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new SAMDAs, in which case the costs and benefits of new SAMDAs and the bases for not incorporating new SAMDAs in the manufacturing license must be addressed. In either case, the environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

110. Section 51.31 is revised to read as follows:

§ 51.31 Determinations based on environmental assessment.

(a) *General.* Upon completion of an environmental assessment for proposed actions other than those involving a standard design certification or a manufacturing license under part 52 of this chapter, the appropriate NRC staff director will determine whether to prepare an environmental impact statement or a finding of no significant impact on the proposed action. As provided in § 51.33, a determination to prepare a draft finding of no significant impact may be made.

(b) *Standard design certification.* (1) For actions involving the issuance or amendment of a standard design certification, the Commission shall prepare a draft environmental assessment for public comment as part of the proposed rule. The proposed rule must state that:

(i) The Commission has determined that in § 51.32 there is no significant environmental impact associated with the issuance of the standard design certification or its amendment, as applicable; and

(ii) Comments on the environmental assessment will be limited to the consideration of SAMDAs as required by § 51.30(d) or (e), as applicable.

(2) The Commission will prepare a final environmental assessment following the close of the public comment period for the proposed standard design certification.

(c) *Manufacturing license.* (1) Upon completion of the environmental assessment for actions involving issuance or amendment of a manufacturing license (manufacturing license environmental assessment), the NRC's Director of Nuclear Reactor Regulation (staff director) will determine the costs and benefits of severe accident mitigation design alternatives (SAMDAs) and the bases for not incorporating SAMDAs in the design of the reactor to be manufactured under the manufacturing license. The NRC staff director may determine to prepare a draft environmental assessment.

(2) The manufacturing license environmental assessment must state that:

(i) The Commission has determined that in § 51.32 there is no significant environmental impact associated with the issuance of a manufacturing license or an amendment to a manufacturing license, as applicable;

(ii) The environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license; and

(iii) Comments on the environmental assessment will be limited to the consideration of SAMDAs as required by § 51.30(d) or (e), as applicable.

(3) If the NRC staff director makes a determination to prepare and issue a draft environmental assessment for public review and comment before making a final determination on the manufacturing license application, the assessment will be marked, "Draft." The NRC notice of availability on the draft environmental assessment will include a request for comments which specifies where comments should be submitted and when the comment period expires. The notice will state that copies of the environmental assessment and any related

environmental documents are available for public inspection and where inspections can be made. A copy of the final environmental assessment will be sent to the U.S. Environmental Protection Agency, the applicant, any party to a proceeding, each commenter, and any other Federal, State, and local agencies, and Indian tribes, State, regional, and metropolitan clearinghouses expressing an interest in the action. Additional copies will be made available in accordance with § 51.123.

(4) When a hearing is held under the regulations in part 2 of this chapter on the proposed issuance of the manufacturing license or amendment, the NRC staff director will prepare a final environmental assessment which may be subject to modification as a result of review and decision as appropriate to the nature and scope of the proceeding. The presiding officer will issue the final environmental assessment.

(5) Only a party admitted into the proceeding with respect to a contention on the environmental assessment may take a position and offer evidence on the matters within the scope of the environmental assessment.

111. In § 51.32, paragraph (b) is added to read as follows:

§ 51.32 Finding of no significant impact.

* * * * *

(b) The Commission finds that there is no significant environmental impact associated with the issuance of:

- (1) A standard design certification under subpart B of part 52 of this chapter;
- (2) An amendment to a design certification;
- (3) A manufacturing license under subpart F of part 52 of this chapter; or
- (4) An amendment to a manufacturing license.

112. In § 51.45 paragraph (c) is revised to read as follows:

§ 51.45 Environmental report.

* * * * *

(c) *Analysis.* The environmental report shall include an analysis that considers and balances the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental effects. Except for environmental reports prepared at the early site permit stage under § 51.50(b), or environmental reports prepared at the license renewal stage under § 51.53(c), the analysis in the environmental report should also include consideration of the economic, technical, and other benefits and costs of the proposed action and of alternatives. Environmental reports prepared at the license renewal stage under § 51.53(c) need not discuss the economic or technical benefits and costs of either the proposed action or alternatives except insofar as these benefits and costs are either essential for a determination regarding the inclusion of an alternative in the range of alternatives considered or relevant to mitigation. In addition, environmental reports prepared under to § 51.53(c) need not discuss issues not related to the environmental effects of the proposed action and its alternatives. The analyses for environmental reports shall, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that cannot be quantified, those considerations or factors shall be discussed in qualitative terms. The environmental report should contain sufficient data to aid the Commission in its development of an independent analysis.

* * * * *

113. Section 51.50 is revised to read as follows:

§ 51.50 Environmental report—construction permit, early site permit, or combined license stage.

(a) *Construction permit stage.* Each applicant for a permit to construct a production or utilization facility covered by § 51.20 shall submit with its application a separate document, entitled “Applicant’s Environmental Report–Construction Permit Stage,” which shall contain the information specified in §§ 51.45, 51.51 and 51.52. Each environmental report shall identify procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter.

(b) *Early site permit stage.* Each applicant for an early site permit shall submit with its application a separate document, entitled “Applicant’s Environmental Report–Early Site Permit Stage,” which shall contain the information specified in §§ 51.45, 51.51, and 51.52, as modified in this paragraph. Environmental reports need not include an assessment of the economic, technical, and other benefits and costs of the proposed action or an analysis of other energy alternatives. Environmental reports must focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the postulated site parameters. Environmental reports must include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed. If the applicant seeks to perform the activities at the site allowed by § 50.10(e)(1) of this chapter, the environmental report must include a plan for redress of the site that will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws. For other than light-water-cooled nuclear power reactors, the environmental report shall contain the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear power reactor. Each environmental report shall identify procedures for

reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter.

(c) *Combined license stage.* Each applicant for a combined license covered by § 51.20 shall submit with its application a separate document, entitled “Applicant’s Environmental Report–Combined License Stage.” Each environmental report shall contain the information specified in §§ 51.45, 51.51 and 51.52; for other than light-water-cooled nuclear power reactors, the environmental report shall contain the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear power reactor. Each environmental report shall identify procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter. The combined license environmental report may reference information contained in a final environmental document previously prepared by the NRC staff.

(1) *Application referencing an early site permit.* The applicant must have a reasonable process for identifying any new and significant information regarding the NRC’s conclusions in the early site permit environmental impact statement. If the combined license application references an early site permit, then the “Applicant’s Environmental Report–Combined License Stage” need not contain information or analyses submitted to the Commission in “Applicant’s Environmental Report–Early Site Permit Stage,” but must contain, in addition to the environmental information and analyses otherwise required:

(i) Information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit;

(ii) Information to resolve any other significant environmental issue not considered in the early site permit proceeding, either for the site or design; and

(iii) Any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit environmental impact statement.

(2) *Application referencing standard design certification.* If the combined license references a standard design certification, then the combined license environmental report may incorporate by reference the environmental assessment previously prepared by the NRC for the referenced design certification. If the design certification environmental assessment is referenced, then the combined license environmental report must contain information to demonstrate that the site characteristics for the combined license site fall within the site parameters in the design certification environmental assessment.

(3) *Application referencing a manufactured reactor.* If the combined license application proposes to use a manufactured reactor, then the combined license environmental report may incorporate by reference the environmental assessment previously prepared by the NRC for the underlying manufacturing license. If the manufacturing license environmental assessment is referenced, then the combined license environmental report must contain information to demonstrate that the site characteristics for the combined license site fall within the site parameters in the manufacturing license environmental assessment. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

(4) *Application requesting authority to conduct activities under § 50.10(e) of this chapter.* If the applicant seeks to perform activities at the site allowed by § 50.10(e) of this chapter, then the environmental report must include a plan for redress of the site that will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

114. In § 51.51 paragraph (a) is revised to read as follows:

§ 51.51 Uranium fuel cycle environmental data—Table S-3.

(a) Under § 51.50, every environmental report prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, and submitted on or after September 4, 1979, shall take Table S-3, Table of Uranium Fuel Cycle Environmental Data, as the basis for evaluating the contribution of the environmental effects of uranium mining and milling, the production of uranium hexafluoride, isotopic enrichment, fuel fabrication, reprocessing of irradiated fuel, transportation of radioactive materials and management of low-level wastes and high-level wastes related to uranium fuel cycle activities to the environmental costs of licensing the nuclear power reactor. Table S-3 shall be included in the environmental report and may be supplemented by a discussion of the environmental significance of the data set forth in the table as weighed in the analysis for the proposed facility.

* * * * *

115. In § 51.52, the introductory paragraph is revised to read as follows:

§ 51.52 Environmental effects of transportation of fuel and waste—Table S-4.

Under § 51.50, every environmental report prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, and submitted after February 4, 1975, shall contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. That statement shall indicate that the reactor and this transportation either meet all of the conditions in paragraph (a) of this section or all of the conditions of paragraph (b) of this section.

* * * * *

116. In § 51.53 paragraph (a) and the introductory text of paragraph (c)(3) are revised to read as follows:

§ 51.53 Postconstruction environmental reports.

(a) *General.* Any environmental report prepared under the provisions of this section may incorporate by reference any information contained in a prior environmental report or supplement thereto that relates to the production or utilization facility or site, or any information contained in a final environmental document previously prepared by the NRC staff that relates to the production or utilization facility or site. Documents that may be referenced include, but are not limited to, the final environmental impact statement; supplements to the final environmental impact statement, including supplements prepared at the license renewal stage; NRC staff-prepared final generic environmental impact statements; and environmental assessments and records of decisions prepared in connection with the construction permit, operating license, early site permit, combined license and any license amendment for that facility.

* * * * *

(c) * * *

(3) For those applicants seeking an initial renewal license and holding an operating license, construction permit, or combined license as of June 30, 1995, the environmental report shall include the information required in paragraph (c)(2) of this section subject to the following conditions and considerations:

* * * * *

117. Section 51.54 is revised to read as follows:

§ 51.54 Environmental report-manufacturing license.

(a) Each applicant for a manufacturing license under subpart F of part 52 of this chapter shall submit with its application a separate document entitled, “Applicant’s Environmental Report – Manufacturing License.” The environmental report must address the costs and benefits of severe accident mitigation design alternatives (SAMDA), and the bases for not incorporating SAMDA into the design of the reactor to be manufactured. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

(b) Each applicant for an amendment to a manufacturing license shall submit with its application a separate document entitled, “Applicant’s Supplemental Environmental Report–Amendment to Manufacturing License.” The environmental report must address whether the design change which is the subject of the proposed amendment either renders a SAMDA previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new SAMDA that may be reasonably incorporated into the design of the manufactured reactor. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

118. Section 51.55 is redesignated as § 51.58, and is revised to read as follows:

§ 51.58 Environmental report-number of copies; distribution.

(a) Each applicant for a license or permit to site, construct or operate a production or utilization facility covered by §§ 51.20(b)(1), (b)(2), (b)(3), or (b)(4), each applicant for renewal of an operating or combined license for a nuclear power plant, each applicant for a license amendment authorizing the decommissioning of a production or utilization facility covered by § 51.20, and each applicant for a license or license amendment to store spent fuel at a nuclear power plant after expiration of the operating license for the nuclear power plant shall submit a copy to the Director of the Office of Nuclear Reactor Regulation, or a copy to the Director of the

Office of Nuclear Material Safety and Safeguards, as appropriate, of an environmental report or any supplement to an environmental report. These reports must be sent either by mail addressed: ATTN: Document Control Desk; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030, by e-mail to EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date. The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent distribution to parties and Boards in the NRC proceedings; Federal, State, and local officials; and any affected Indian tribes, in accordance with written instructions issued by the Director of the Office of Nuclear Reactor Regulation or the Director of the Office of Nuclear Material Safety and Safeguards, as appropriate.

(b) Each applicant for a license to manufacture a nuclear power reactor, or for an amendment to a license to manufacture, seeking approval of the final design of the nuclear power reactor, under subpart F of part 52 of this chapter shall submit to the Commission an environmental report or any supplement to an environmental report in the manner specified in

§ 50.4 of this chapter. The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent distribution to parties and Boards in the NRC proceeding; Federal, State, and local officials; and any affected Indian tribes, in accordance with written instructions issued by the Director of Nuclear Reactor Regulation.

119. Section 51.55 is added to read as follows:

§ 51.55 Environmental report–standard design certification.

(a) Each applicant for a standard design certification under subpart B of part 52 of this chapter shall submit with its application a separate document entitled, “Applicant’s Environmental Report–Standard Design Certification.” The environmental report must address the costs and benefits of severe accident mitigation design alternatives (SAMDA), and the bases for not incorporating SAMDAs in the design to be certified.

(b) Each applicant for an amendment to a design certification shall submit with its application a separate document entitled, “Applicant’s Supplemental Environmental Report–Amendment to Standard Design Certification.” The environmental report must address whether the design change which is the subject of the proposed amendment either renders a SAMDA previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new SAMDAs that may be reasonably incorporated into the design certification.

120. Section 51.66 is revised to read as follows:

§ 51.66 Environmental report-number of copies; distribution.

Each applicant for a license or other form of permission, or an amendment to or renewal of a license or other form of permission issued under parts 30, 32, 33, 34, 35, 36, 39, 40, 61, 70

and/or 72 of this chapter, and covered by §§ 51.60(b)(1) through (6); or by § 51.61 or § 51.62 shall submit to the Director of Nuclear Material Safety and Safeguards an environmental report or any supplement to an environmental report in the manner specified in § 51.58(a). The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent distribution to Federal, State, and local officials, and any affected Indian tribes in accordance with written instructions issued by the Director of Nuclear Material Safety and Safeguards.

121. In § 51.71 paragraph (d) and Footnote 3 are revised to read as follows:

§ 51.71 Draft environmental impact statement—contents.

* * * * *

(d) *Analysis.* Unless excepted in this paragraph, the draft environmental impact statement will include a preliminary analysis that considers and weighs the environmental effects of the proposed action; the environmental impacts of alternatives to the proposed action; and alternatives available for reducing or avoiding adverse environmental effects and consideration of the economic, technical, and other benefits and costs of the proposed action and alternatives and indicate what other interests and considerations of Federal policy, including factors not related to environmental quality if applicable, are relevant to the consideration of environmental effects of the proposed action identified under paragraph (a) of this section. The draft environmental impact statement prepared at the early site permit stage must focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the postulated site parameters, and will not include an assessment of the benefits (for example, need for power) of the proposed action or an evaluation of other alternative energy sources unless considered by the applicant, but must include an evaluation of alternative sites to determine whether there is any alternative to the site

proposed. The draft supplemental environmental impact statement prepared at the combined license stage when an early site permit is referenced need not include detailed information or analyses that were resolved in the final environmental impact statement prepared by the Commission in connection with the early site permit, provided that the design of the facility falls within the design parameters specified in the early site permit, the site falls within the site characteristics specified within the early site permit, and there is no significant new environmental issue or information not considered on the site or the design only to the extent that they differ from that discussed in the final environmental impact statement prepared by the Commission in connection with the early site permit. The draft supplemental environmental impact statement prepared at the license renewal stage under § 51.95(c) need not discuss the economic or technical benefits and costs of either the proposed action or alternatives except if benefits and costs are either essential for a determination regarding the inclusion of an alternative in the range of alternatives considered or relevant to mitigation. In addition, the supplemental environmental impact statement prepared at the license renewal stage need not discuss other issues not related to the environmental effects of the proposed action and associated alternatives. The draft supplemental environmental impact statement for license renewal prepared under § 51.95(c) will rely on conclusions as amplified by the supporting information in the GEIS for issues designated as Category 1 in appendix B to subpart A of this part. The draft supplemental environmental impact statement must contain an analysis of those issues identified as Category 2 in appendix B to subpart A of this part that are open for the proposed action. The analysis for all draft environmental impact statements will, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that cannot be quantified, these considerations or factors will be discussed in qualitative terms. Consideration will be given to compliance with environmental quality standards and requirements that have been imposed by Federal, State,

regional, and local agencies having responsibility for environmental protection, including applicable zoning and land-use regulations and water pollution limitations or requirements issued or imposed under the Federal Water Pollution Control Act. The environmental impact of the proposed action will be considered in the analysis with respect to matters covered by environmental quality standards and requirements irrespective of whether a certification or license from the appropriate authority has been obtained.³ While satisfaction of Commission standards and criteria pertaining to radiological effects will be necessary to meet the licensing requirements of the Atomic Energy Act, the analysis will, for the purposes of NEPA, consider the radiological effects of the proposed action and alternatives.

* * * * *

³Compliance with the environmental quality standards and requirements of the Federal Water Pollution Control Act (imposed by EPA or designated permitting states) is not a substitute for, and does not negate the requirement for NRC to weigh all environmental effects of the proposed action, including the degradation, if any, of water quality, and to consider alternatives to the proposed action that are available for reducing adverse effects. Where an environmental assessment of aquatic impact from plant discharges is available from the permitting authority, the NRC will consider the assessment in its determination of the magnitude of environmental impacts for striking an overall cost-benefit balance at the construction permit and operating license and early site permit and combined license stages, and in its determination of whether the adverse environmental impacts of license renewal are so great that preserving the option of license renewal for energy planning decision-makers would be unreasonable at the license renewal stage. When the assessment of aquatic impacts is no longer available from the permitting authority, NRC will establish on its own, or in conjunction with the permitting authority and other agencies having relevant expertise, the magnitude of potential impacts for striking an overall cost-benefit balance for the facility at the construction permit and operating license and early site permit and combined license stages, and in its determination of whether the adverse environmental impacts of license renewal are so great that preserving the option of license renewal for energy planning decision-makers would be unreasonable at the license renewal stage.

122. Section 51.75 is revised to read as follows:

§ 51.75 Draft environmental impact statement—construction permit, early site permit, or combined license.

(a) *Construction permit stage.* A draft environmental impact statement relating to issuance of a construction permit for a production or utilization facility will be prepared in accordance with the procedures and measures described in §§ 51.70, 51.71, 51.72, and 51.73. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 shall be evaluated on the basis of impact values set forth in Table S-3, Table of Uranium Fuel Cycle Environmental Data, which shall be set out in the draft environmental impact statement. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the Table shall be required.⁵ The impact statement shall take account of dose commitments and health effects from fuel cycle effluents set forth in Table S-3 and shall in addition take account of economic, socioeconomic, and possible cumulative impacts and other fuel cycle impacts as may reasonably appear significant.

(b) *Early site permit stage.* A draft environmental impact statement relating to issuance of an early site permit for a production or utilization facility will be prepared in accordance with the procedures and measures described in §§ 51.70, 51.71, 51.72, and 51.73. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 shall be evaluated on the basis of impact values set forth in Table S-3, Table of Uranium Fuel Cycle Environmental Data, which shall be set out in the draft environmental impact statement. With

⁵Values for releases of Rn-222 and TC-99 are not given in the Table. The amount and significance of Rn-222 releases from the fuel cycle and TC-99 releases from waste management or reprocessing activities shall be considered in the draft environmental impact statement and may be the subject of litigation in individual licensing proceedings.

the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the table shall be required.⁵ The impact statement shall take account of dose commitments and health effects from fuel cycle effluents set forth in Table S-3 and shall in addition take account of economic, socioeconomic, and possible cumulative impacts and other fuel cycle impacts as may reasonably appear significant.

(c) *Combined license stage.* A draft environmental impact statement relating to issuance of a combined license that does not reference an early site permit will be prepared in accordance with the procedures and measures described in §§ 51.70, 51.71, 51.72, and 51.73. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 shall be evaluated on the basis of impact values set forth in Table S–3, Table of Uranium Fuel Cycle Environmental Data, which shall be set out in the draft environmental impact statement. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the Table shall be required.⁵ The impact statement shall take account of dose commitments and health effects from fuel cycle effluents set forth in Table S–3 and shall in addition take account of economic, socioeconomic, and possible cumulative impacts and other fuel cycle impacts as may reasonably appear significant. The impact statement will include a discussion of the storage of spent fuel for the nuclear power plant within the scope of the generic determination in § 51.23(a) and in accordance with § 51.23(b).

(1) *Combined license application referencing an early site permit.* If the combined license application references an early site permit and the design of the facility falls within the site characteristics and design parameters specified in the early site permit, then the draft supplemental combined license environmental impact statement shall incorporate by reference

the early site permit final environmental impact statement, and summarize the findings and conclusions of the early site permit final environmental impact statement.

(2) *Combined license application referencing a standard design certification.* If the combined license application references a standard design certification and the site characteristics of the combined license's site falls within the site parameters specified in the design certification environmental assessment, then the draft combined license environmental impact statement shall incorporate by reference the design certification environmental assessment, and summarize the findings and conclusions of the environmental assessment with respect to severe accident mitigation design alternatives.

(3) *Combined license application referencing a manufactured reactor.* If the combined license application proposes to use a manufactured reactor and the site characteristics of the combined license's site falls within the site parameters specified in the manufacturing license environmental assessment, then the draft combined license environmental impact statement shall incorporate by reference the manufacturing license environmental assessment, and summarize the findings and conclusions of the environmental assessment with respect to SAMDAs. The combined license environmental impact statement report will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

123. Section 51.76 is removed and reserved.

§ 51.76 [Reserved]

124. In § 51.95, paragraph (a), the introductory text of paragraph (c), and paragraph (d) are revised to read as follows:

§ 51.95 Postconstruction environmental impact statements.

(a) *General.* Any supplement to a final environmental impact statement or any environmental assessment prepared under the provisions of this section may incorporate by reference any information contained in a final environmental document previously prepared by the NRC staff that relates to the same production or utilization facility. Documents that may be referenced include, but are not limited to, the final environmental impact statement; supplements to the final environmental impact statement, including supplements prepared at the operating license stage; NRC staff-prepared final generic environmental impact statements; environmental assessments and records of decisions prepared in connection with the construction permit, the operating license, the early site permit, or the combined license and any license amendment for that facility. A supplement to a final environmental impact statement will include a request for comments as provided in § 51.73.

* * * * *

(c) *Operating license renewal stage.* In connection with the renewal of an operating license for a nuclear power plant under parts 52 or 54 of this chapter, the Commission shall prepare an EIS, which is a supplement to the Commission's NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants" (May 1996) which is available in the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland.

* * * * *

(d) *Postoperating license stage.* In connection with the amendment of an operating or combined license authorizing decommissioning activities at a production or utilization facility covered by § 51.20, either for unrestricted use or based on continuing use restrictions applicable to the site, or with the issuance, amendment or renewal of a license to store spent

fuel at a nuclear power reactor after expiration of the operating or combined license for the nuclear power reactor, the NRC staff will prepare a supplemental environmental impact statement for the post operating or post combined license stage or an environmental assessment, as appropriate, which will update the prior environmental review. The supplement or assessment may incorporate by reference any information contained in the final environmental impact statement—for the operating or combined license stage, as appropriate, or in the records of decision prepared in connection with the early site permit, construction permit, operating license, or combined license for that facility. The supplement will include a request for comments as provided in § 51.73. Unless otherwise required by the Commission in accordance with the generic determination in § 51.23(a) and the provisions of § 51.23(b), a supplemental environmental impact statement for the postoperating or post combined license stage or an environmental assessment, as appropriate, will address the environmental impacts of spent fuel storage only for the term of the license, license amendment or license renewal applied for.

125. Section 51.105 is revised to read as follows:

§ 51.105 Public hearings in proceedings for issuance of construction permits or early site permits.

(a) In addition to complying with applicable requirements of § 51.104, in a proceeding for the issuance of a construction permit or early site permit for a nuclear power reactor, testing facility, fuel reprocessing plant or isotopic enrichment plant, the presiding officer will:

(1) Determine whether the requirements of section 102(2) (A), (C), and (E) of NEPA and the regulations in this subpart have been met;

(2) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken;

(3) Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit or early site permit should be issued, denied, or appropriately conditioned to protect environmental values;

(4) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate; and

(5) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the construction permit or early site permit should be issued as proposed by the NRC's Director of Nuclear Reactor Regulation.

(b) The presiding officer in an early site permit hearing shall not admit contentions proffered by any party concerning the benefits assessment (e.g., need for power) or alternative energy sources if those issues were not addressed by the applicant in the early site permit application.

126. Section 51.105a is added to read as follows:

§ 51.105a Public hearings in proceedings for issuance of manufacturing licenses.

(a) In addition to complying with applicable requirements of § 51.31(c), in a proceeding for the issuance of a manufacturing license, the presiding officer will:

(1) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate to identify all reasonable SAMDAs for the design of the reactor to be manufactured and evaluate the environmental, technical, economic, and other benefits and costs of each SAMDA; and

(2) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the manufacturing license should be issued as proposed by the NRC's Director of Nuclear Reactor Regulation.

127. Section 51.107 is added to read as follows:

§ 51.107 Public hearings in proceedings for issuance of combined licenses.

(a) In addition to complying with applicable requirements of § 51.104, in a proceeding for the issuance of a combined license for a nuclear power reactor, the presiding officer will:

(1) Determine whether the requirements of section 102(2) (A), (C), and (E) of NEPA and the regulations in this subpart have been met;

(2) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken;

(3) Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the combined license should be issued, denied, or appropriately conditioned to protect environmental values;

(4) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate; and

(5) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the combined license should be issued as proposed by the NRC's Director of Nuclear Reactor Regulation.

(b) If the combined license application references an early site permit, then the presiding officer in a combined license hearing shall not admit contentions proffered by any party on environmental issues which have been accorded finality under § 52.39 of this chapter, unless this contention- -

(1) Demonstrates that the design of the facility falls outside the design parameters specified in the early site permit;

(2) Demonstrates that the site no longer falls within the site characteristics specified in the early site permit; or

(3) Raises any other significant environmental issue not considered which is material to the site or the design only to the extent that it differs from those discussed or it reflects significant new information in addition to that discussed in the final environmental impact statement prepared by the Commission in connection with the early site permit.

(c) If the combined license application references a standard design certification, or proposes to use a manufactured reactor, then the presiding officer in a combined license hearing shall not admit contentions proffered by any party concerning severe accident mitigation design alternatives unless the contention demonstrates that the site characteristics fall outside of the site parameters in the standard design certification or underlying manufacturing license for the manufactured reactor.

128. Section 51.108 is added under the section "Production and Utilization Facilities," to read as follows:

§ 51.108 Public hearings on a Commission findings that inspections, tests, and acceptance criteria of combined licenses are met.

In any public hearing requested under 10 CFR 52.103(b), the Commission will not admit any contentions on environmental issues, the adequacy of the environmental impact statement for the combined license issued under subpart C of part 52, or the adequacy of any other environmental impact statement or environmental assessment referenced in the combined license application. The Commission will not make any environmental findings in connection with the finding under 10 CFR 52.103(g).

129. Part 52 is revised to read as follows:

PART 52 – Licenses, Certifications, and Approvals for Nuclear Power Plants

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Appendix A to Part 52 - Design Certification Rule for the U.S. Advanced Boiling Water Reactor

Appendix B to Part 52 - Design Certification Rule for the System 80+ Design

Appendix C to Part 52 - Design Certification Rule for the AP600 Design

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

General Provisions

§ 52.0 Scope; applicability of 10 CFR Chapter I provisions.

(a) This part governs the issuance of early site permits, standard design certifications, combined licenses, standard design approvals, and manufacturing licenses for nuclear power facilities licensed under Section 103 of the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). This part also gives notice to all persons who knowingly provide to any holder of or applicant for an approval, certification, permit, or license, or to a contractor, subcontractor, or consultant of any of them, components, equipment, materials, or other goods or services that relate to the activities of a holder of or applicant for an approval, certification, permit, or license, subject to this part, that they may be individually subject to NRC enforcement action for violation of the provisions in 10 CFR 50.5.

(b) Unless otherwise specifically provided for in this part, the regulations in 10 CFR chapter I apply to a holder of or applicant for an approval, certification, permit, or license. A

holder of or applicant for an approval, certification, permit, or license issued under this part shall comply with all requirements in 10 CFR chapter I that are applicable. A license, approval, certification, or permit issued under this part is subject to all requirements in 10 CFR chapter I which, by their terms, are applicable to early site permits, design certifications, combined licenses, design approvals, or manufacturing licenses.

52.1 Definitions.

(a) As used in this part - -

Combined license means a combined construction permit and operating license with conditions for a nuclear power facility issued under subpart C of this part.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits - -

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Design characteristics are the actual features of a reactor or reactors. Design characteristics are specified in a standard design approval, a standard design certification, or a combined license application.

Design parameters are the postulated features of a reactor or reactors that could be built at a proposed site. Design parameters are specified in an early site permit.

Early site permit means a Commission approval, issued under subpart A of this part, for a site or sites for one or more nuclear power facilities.

License means a license, including an early site permit, combined license or manufacturing license under this part or a renewed license issued by the Commission under this part or part 54 of this chapter.

Licensee means a person who is authorized to conduct activities under a license issued by the Commission.

Manufacturing license means a license, issued under subpart F of this part, authorizing the manufacture of nuclear power reactors but not their construction, installation, or operation at the sites on which the reactors are to be operated.

Modular design means a nuclear power station that consists of two or more essentially identical nuclear reactors (modules) and each module is a separate nuclear reactor capable of being operated independent of the state of completion or operating condition of any other module co-located on the same site, even though the nuclear power station may have some shared or common systems.

Prototype plant means a nuclear power plant that is used to test new safety features, such as the testing required under 10 CFR 50.43(e). The prototype plant is similar to a first-of-a-kind or standard plant design in all features and size, but may include additional safety features to protect the public and the plant staff from the possible consequences of accidents during the testing period.

Site characteristics are the actual physical, environmental and demographic features of a site. Site characteristics are specified in an early site permit or in a final safety analysis report for a combined license.

Site parameters are the postulated physical, environmental and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or a manufacturing license.

Standard design means a design which is sufficiently detailed and complete to support certification in accordance with subpart B or E of this part, and which is usable for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

Standard design approval or design approval means an NRC staff approval, issued under subpart E of this part, of a final standard design for a nuclear power reactor of the type

described in 10 CFR 50.22. The approval may be for either the final design for the entire reactor facility or the final design of major portions thereof.

Standard design certification or design certification means a Commission approval, issued under subpart B of this part, of a final standard design for a nuclear power facility. This design may be referred to as a *certified standard design*.

(b) All other terms in this part have the meaning set out in 10 CFR 50.2, or Section 11 of the Atomic Energy Act, as applicable.

§ 52.2 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 52.3 Written communications.

(a) *General requirements.* All correspondence, reports, applications, and other written communications from an applicant, licensee, or holder of a standard design approval to the Nuclear Regulatory Commission concerning the regulations in this part, individual license conditions, or the terms and conditions of an early site permit, must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/eie.html>, by calling (301) 415-6030,

by e-mail at EIE@nrc.gov, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(b) *Distribution requirements.* Copies of all correspondence, reports, and other written communications concerning the regulations in this part or individual license conditions, or the terms and conditions of an early site permit, must be submitted to the persons listed in paragraph (b)(1) of this section (addresses for the NRC Regional Offices are listed in appendix D to part 20 of this chapter).

(1) *Applications for amendment of permits and licenses; reports; and other communications.* All written communications (including responses to: generic letters, bulletins, information notices, regulatory information summaries, inspection reports, and miscellaneous requests for additional information) that are required of holders of combined licenses or manufacturing licenses issued under this part must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (b)(7) of this section: to the NRC's Document Control Desk (if on paper, the signed original), with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under subpart F of this part.

(2) *Applications and amendments to applications.* Applications for early site permits, combined licenses, manufacturing licenses and amendments to any of these types of applications must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under

subpart F of this part, except as otherwise specified in paragraphs (b)(3) through (b)(7) of this section. If the application or amendment is on paper, the submission to the Document Control Desk must be the signed original.

(3) *Acceptance review application.* Written communications required for an application for determination of suitability for docketing must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(4) *Security plan and related submissions.* Written communications, as defined in paragraphs (b)(4)(i) through (iv) of this section, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(i) Physical security plan under § 50.34 of this chapter;

(ii) Safeguards contingency plan under § 50.34 of this chapter;

(iii) Change to security plan, guard training and qualification plan, or safeguards contingency plan made without prior Commission approval under § 50.54(p) of this chapter;

(iv) Application for amendment of physical security plan, guard training and qualification plan, or safeguards contingency plan under § 50.90 of this chapter.

(5) *Emergency plan and related submissions.* Written communications as defined in paragraphs (b)(5)(i) through (iii) of this section must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(i) Emergency plan under § 50.34 of this chapter;

(ii) Change to an emergency plan under § 50.54(q) of this chapter;

(iii) Emergency implementing procedures under appendix E, Section V of this part.

(6) *Updated FSAR.* An updated final safety analysis report (FSAR) or replacement pages under § 50.71(e) of this chapter, or the regulations in this part must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under subpart F of this part. Paper copy submissions may be made using replacement pages; however, if a licensee chooses to use electronic submission, all subsequent updates or submissions must be performed electronically on a total replacement basis. If the communication is on paper, the submission to the Document Control Desk must be the signed original. If the communications are submitted electronically, see Guidance for Electronic Submissions to the Commission.

(7) *Quality assurance related submissions.*

(i) A change to the safety analysis report quality assurance program description under § 50.54(a)(3) or § 50.55(f)(3) of this chapter, or a change to a licensee's NRC-accepted quality assurance topical report under § 50.54(a)(3) or § 50.55(f)(3) of this chapter, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(ii) A change to an NRC-accepted quality assurance topical report from nonlicensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent.

(8) *Certification of permanent cessation of operations.* The licensee's certification of permanent cessation of operations under § 52.110(a)(1), must state the date on which

operations have ceased or will cease, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(9) *Certification of permanent fuel removal.* The licensee's certification of permanent fuel removal under § 52.110(a)(1), must state the date on which the fuel was removed from the reactor vessel and the disposition of the fuel, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(c) *Form of communications.* All paper copies submitted to meet the requirements set forth in paragraph (b) of this section must be typewritten, printed or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements imposed on paper submissions may be granted for the submission of micrographic, photographic, or similar forms.

(d) *Regulation governing submission.* Applicants, licensees, and holders of standard design approvals submitting correspondence, reports, and other written communications under the regulations of this part are requested but not required to cite whenever practical, in the upper right corner of the first page of the submission, the specific regulation or other basis requiring submission.

§ 52.4 Deliberate misconduct.

(a) *Applicability.* This section applies to any:

(1) Licensee;

(2) Applicant for a standard design certification;

(3) Applicant for a license;

(4) Applicant for a standard design approval;

(5) Employee of a licensee.

(6) Employee of an applicant for a license, a standard design certification, or a standard design approval;

(7) Any contractor (including a supplier or consultant), subcontractor, or employee of a contractor or subcontractor of any licensee; or

(8) Any contractor (including a supplier or consultant), subcontractor, or employee of a contractor or subcontractor of any applicant for a license, a standard design certification, or a standard design approval.

(b) *Definitions.* For purposes of this section:

Deliberate misconduct means an intentional act or omission that a person or entity knows:

(i) Would cause a licensee or an applicant for a license, standard design certification, or standard design approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license, standard design certification, or standard design approval; or

(ii) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, or contractor, or subcontractor.

License means a license issued under this part, including an early site permit.

Licensee means any person holding a license issued under this part, including an early site permit.

(c) *Prohibition against deliberate misconduct.* Any person or entity subject to this section, who knowingly provides to any licensee, any applicant for a license, standard design certification or standard design approval, or a contractor, or subcontractor of a person or entity subject to this section, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities under this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, holder of a standard design approval, or applicant to be in violation of any regulation

or order; or any term, condition, or limitation of any license issued by the Commission, any standard design approval, or standard design certification; or

(2) Deliberately submit to the NRC; a licensee, an applicant for a license, standard design certification or standard design approval; or a licensee's, standard design approval holder's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person or entity who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

§ 52.5 Employee protection.

(a) Discrimination by a Commission licensee, holder of a standard design approval, an applicant for a license, standard design certification, or standard design approval, a contractor or subcontractor of a Commission licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in Section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in the introductory text of paragraph (a) of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in the introductory text of paragraph (a) of this section or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in the introductory text of paragraph (a) of this section; and

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, a holder of a standard design approval, an applicant for a Commission license, standard design certification, or a standard design approval, or a contractor or subcontractor of a Commission licensee, holder of a standard design approval, or any applicant may be grounds for—

(1) Denial, revocation, or suspension of the license or standard design approval;

(2) Withdrawal or revocation of a proposed or final rule;

(3) Imposition of a civil penalty on the licensee, holder of a standard design approval, or applicant; or

(4) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee, each holder of a standard design approval, and each applicant for a license, standard design certification, or standard design approval, shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c). This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than thirty (30) days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, standard design certification, or standard design approval under part 52, and for 30 days following license termination or the expiration or termination of the standard design certification or standard design approval under part 52.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-5877, via e-mail to forms@nrc.gov, or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the NRC's home page.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor under Section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

(g) Part 19 of this chapter sets forth requirements and regulatory provisions applicable to licensees, holders of a standard design approval, applicants for a license, standard design certification, or standard design approval, and contractors or subcontractors of a Commission licensee, or holder of a standard design approval, and are in addition to the requirements in this section.

§ 52.6 Completeness and accuracy of information.

(a) Information provided to the Commission by a licensee (including a construction permit holder, and a combined license holder), a holder of a standard design approval under this part, and an applicant for a license or an applicant for a standard design certification or a standard design approval under this part, and information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the licensee, the holder of a standard design approval under this part, the applicant for a standard design certification under this part following Commission adoption of a final design certification rule, and an applicant for a license, a standard design certification, or a standard design approval under this part shall be complete and accurate in all material respects.

(b) Each applicant or licensee, each holder of a standard design approval under this part, and each applicant for a standard design certification under this part following Commission adoption of a final design certification regulation, shall notify the Commission of information

identified by the applicant or the licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant, licensee, or holder violates this paragraph only if the applicant, licensee, or holder fails to notify the Commission of information that the applicant, licensee, or holder has been identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

§ 52.7 Specific exemptions.

The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part. The Commission's consideration will be governed by § 50.12 of this chapter, unless other criteria are provided for in this part, in which case the Commission's consideration will be governed by the criteria in this part. Only if those criteria are not met will the Commission's consideration be governed by § 50.12. The Commission's consideration of requests for exemptions from requirements of the regulations of other parts in this chapter, which are applicable by virtue of this part, shall be governed by the exemption requirements of those parts.

§ 52.8 Combining licenses.

The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 52.9 Jurisdictional limits.

No license, standard design approval, or standard design certification under this part shall be deemed to have been issued for activities which are not under or within the jurisdiction of the United States.

§ 52.10 Attacks and destructive acts.

Neither an applicant for a license to manufacture, construct, and operate a utilization facility under this part, nor for an amendment to this license, or an applicant for an early site permit, a standard design certification, or standard design approval under this part, or for an amendment to the standard design certification or approval, is required to provide for design features or other measures for the specific purpose of protection against the effects of -

- (a) Attacks and destructive acts, including sabotage, directed against the facility by an enemy of the United States, whether a foreign government or other person; or
- (b) Use or deployment of weapons incident to U.S. defense activities.

§ 52.10a Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under Control Number 3150-0151.

(b) The approved information collection requirements contained in this part appear in §§ 52.15, 52.16, 52.17, 52.29, 52.35, 52.39, 52.45, 52.46, 52.47, 52.57, 52.63, 52.75, 52.77, 52.79, 52.80, 52.98, 52.99, 52.110, 52.135, 52.136, 52.137, 52.145, 52.155, 52.156, 52.157, 52.171, 52.177, and appendices A, B, and C.

Subpart A – Early Site Permits

§ 52.11 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of an early site permit for approval of a site for one or more nuclear power facilities

separate from the filing of an application for a construction permit or combined license for the facility.

§ 52.13 Relationship to other subparts.

This subpart applies when any person who may apply for a construction permit under 10 CFR part 50, or for a combined license under this part seeks an early site permit from the Commission separately from an application for a construction permit or a combined license.

§ 52.15 Filing of applications.

(a) Any person who may apply for a construction permit under 10 CFR part 50, or for a combined license under this part, may file an application for an early site permit with the Director, Office of Nuclear Reactor Regulation. An application for an early site permit may be filed notwithstanding the fact that an application for a construction permit or a combined license has not been filed in connection with the site for which a permit is sought.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.

(c) The fees associated with the filing and review of an application for the initial issuance or renewal of an early site permit are set forth in 10 CFR part 170.

§ 52.16 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (d) and (j) of this chapter.

§ 52.17 Contents of applications; technical information.

(a) The application must contain:

(1) A site safety analysis report. The site safety analysis report shall include the following:

(i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;

(ii) The anticipated maximum levels of radiological and thermal effluents each facility will produce;

(iii) The type of cooling systems, intakes, and outflows that may be associated with each facility;

(iv) The boundaries of the site;

(v) The proposed general location of each facility on the site;

(vi) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated;

(vii) The location and description of any nearby industrial, military, or transportation facilities and routes;

(viii) The existing and projected future population profile of the area surrounding the site;

(ix) A description and safety assessment of the site on which a facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(ix)(A) and (a)(1)(ix)(B) of this section. In performing this assessment, an applicant shall assume a fission product release¹ from the core into the containment assuming that the facility is operated at the

¹The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem² total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(x) For nuclear power facilities to be sited on multi-unit sites, an evaluation of the potential hazards to the structures, systems, and components important to safety of operating units resulting from construction activities, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation are not exceeded as a result of construction activities at the multi-unit sites;

²A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accidents.

(xi) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed;

(xii) For applications submitted after [insert date of final rule], a description of the quality assurance program applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Appendix B to 10 CFR Part 50 sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant site shall include a discussion of how the applicable requirements of appendix B of this part will be satisfied; and

(xiii) An evaluation of the site against applicable sections of the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in analytical techniques and procedural measures proposed for a site and those corresponding techniques and measures given in the SRP acceptance criteria. Where such a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP was issued to establish criteria that the NRC staff intends to use in evaluating whether an applicant/licensee meets the Commission's regulations. The SRP is not a substitute for the regulations, and compliance is not a requirement.

(2) A complete environmental report as required by 10 CFR 51.50(b).

(b)(1) The application must identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. If physical characteristics are identified that could pose a significant impediment to the development of emergency plans, the

application must identify measures that would, when implemented, mitigate or eliminate the significant impediment.

(2) The application may also:

(i) Propose major features of the emergency plans in the site safety analysis report, in accordance with the pertinent standards of 10 CFR 50.47, and the requirements of appendix E to 10 CFR part 50, such as the exact size and configuration of the emergency planning zones, that can be reviewed and approved by NRC in consultation with the Federal Emergency Management Agency (FEMA) in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans in the site safety analysis report for review and approval by the NRC, in consultation with FEMA, in accordance with the applicable standards of 10 CFR 50.47, and the requirements of appendix E to 10 CFR part 50. To the extent approval of emergency plans is sought, the application must contain the information required by §§ 50.33(g) and (j) of this chapter.

(3) Emergency plans, and each major feature of an emergency plan, submitted under paragraph (b)(2) of this section must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC's regulations.

(4) Under paragraphs (b)(1) and (b)(2)(i) of this section, the application must include a description of contacts and arrangements made with Federal, State, and local governmental agencies with emergency planning responsibilities. The application must contain any certifications that have been obtained. If these certifications cannot be obtained, the application must contain information, including a utility plan, sufficient to show that the proposed plans

provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site. Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant shall make good faith efforts to obtain from the same governmental agencies certifications that:

(i) The proposed emergency plans are practicable;

(ii) These agencies are committed to participating in any further development of the plans, including any required field demonstrations, and

(iii) That these agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(c) If the applicant requests authorization to perform activities at the site, which are identified in 10 CFR 50.10(e)(1), after issuance of the early site permit and without a separate authorization under 10 CFR 50.10(e)(1), the applicant must identify and describe in the site safety analysis report the activities that are requested, and propose a plan in the environmental report for redress of the site in the event that the activities are performed and the early site permit expires before it is referenced in an application for a construction permit or a combined license. The application must demonstrate that there is reasonable assurance that redress carried out under the plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

(d) The NRC staff will advise the applicant on whether any information beyond that required by this section must be submitted.

§ 52.18 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR part 50 and its appendices and 10 CFR part 100. In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR part 51. The Commission shall

determine, after consultation with FEMA, whether the information required of the applicant by § 52.17(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 52.17(b)(2)(i) are acceptable in accordance with the applicable standards of 10 CFR 50.47 and the requirements of appendix E to 10 CFR part 50, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

§ 52.21 Administrative review of applications: hearings.

An early site permit is subject to all procedural requirements in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1)-(4) of this chapter, and the requirements for issuance of a notice of hearing in §§ 2.104(a) and (d) of this chapter provided that the designated sections may not be construed to require that the environmental report, or draft or final environmental impact statement include an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources. The presiding officer in an early site permit hearing shall not admit contentions proffered by any party concerning an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources if those issues were not addressed by the applicant in the early site permit application. All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in subparts C, G, and L of 10 CFR part 2, as applicable.

§ 52.23 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application for an early site permit to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.24 Issuance of early site permit.

(a) After conducting a hearing under § 52.21 and receiving the report to be submitted by the ACRS under § 52.23, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that:

- (1) An application for an early site permit meets the applicable standards and requirements of the Act and the Commission's regulations;
- (2) Notifications, if any, to other agencies or bodies have been duly made;
- (3) There is reasonable assurance that the site is in conformity with the provisions of the Act, and the Commission's regulations;
- (4) The applicant is technically qualified to engage in any activities authorized;
- (5) The proposed inspections, tests, analyses and acceptance criteria, including any on emergency planning, are necessary and sufficient, within the scope of the early site permit, to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;
- (6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;
- (7) Any significant adverse environmental impact resulting from activities requested under § 52.17(c) can be redressed; and
- (8) The findings required by subpart A of 10 CFR part 51 have been made.

(b) The early site permit shall specify the site characteristics, design parameters, and terms and conditions of the early site permit the Commission deems appropriate. Before issuance of either a construction permit or combined license referencing an early site permit, the Commission shall find that any relevant terms and conditions of the early site permit have been met.

(c) The early site permit shall specify the activities under § 52.17(c) that the permit holder is authorized to perform.

§ 52.25 Extent of activities permitted.

If the activities authorized by § 52.24(c) are performed and the site is not referenced in an application for a construction permit or a combined license issued under subpart C of this part while the permit remains valid, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit shall redress the site in accordance with the terms of the site redress plan required by § 52.17(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 52.27 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 10, nor more than 20 years from the date of issuance.

(b)(1) An early site permit continues to be valid beyond the date of expiration in any proceeding on a construction permit application or a combined license application that references the early site permit and is docketed before the date of expiration of the early site permit, or, if a timely application for renewal of the permit has been filed, before the Commission has determined whether to renew the permit.

(2) An early site permit also continues to be valid beyond the date of expiration in any proceeding on an operating license application which is based on a construction permit that references the early site permit, and in any hearing held under § 52.103 before operation begins under a combined license which references the early site permit.

(c) An applicant for a construction permit or combined license may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

§ 52.28 Transfer of early site permit.

An application to transfer an early site permit will be processed under 10 CFR 50.80.

§ 52.29 Application for renewal.

(a) Not less than 12, nor more than 36 months before the expiration date stated in the early site permit, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR 2.309. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.309.

(c) An early site permit, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in certain proceedings in accordance with the provisions of § 52.27(b).

(d) The Commission shall refer a copy of the application for renewal to the ACRS. The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.31.

§ 52.31 Criteria for renewal.

(a) The Commission shall grant the renewal if it determines that:

(1) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and

(2) Any new requirements the Commission may wish to impose are:

(i) Necessary for adequate protection to public health and safety or common defense and security;

(ii) Necessary for compliance with the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; or

(iii) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal for failure to comply with the provisions of § 52.31(a) does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.

§ 52.33 Duration of renewal.

Each renewal of an early site permit may be for not less than 10, nor more than 20 years.

§ 52.35 Use of site for other purposes.

A site for which an early site permit has been issued under this subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder shall inform the Director of Nuclear Reactor Regulation (Director) of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, in accordance with the provisions of § 52.39. If the permit holder informs the Director that the holder no longer intends to use the site for a nuclear power plant, the Director may terminate the permit.

§ 52.39 Finality of early site permit determinations.

(a) *Commission finality.* (1) Notwithstanding any provision in 10 CFR 50.109, while an early site permit is in effect under §§ 52.27 or 52.33, the Commission may not change or

impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission:

(i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;

(ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;

(iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or

(iv) Issues a variance requested under paragraph (d) of this section.

(2) In making the findings required for issuance of a construction permit, operating license, or combined license, or the findings required by § 52.103, if the application for the construction permit, operating license, or combined license references an early site permit, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c) and (d) of this section. If the early site permit approved an emergency plan (or major features thereof) that are in use by a licensee of a nuclear power plant, the Commission shall treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee's emergency plans in compliance with § 50.54(q) of this chapter occurring after issuance of the early site permit.

(b) *Updating of early site permit-emergency preparedness.* An applicant for a construction permit, operating license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update the emergency preparedness information that was provided under § 52.17(b), and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

(c) *Hearings and petitions.* (1) In any proceeding for the issuance of a construction permit, operating license, or combined license referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application which materially affects the Commission's earlier determination on emergency preparedness, or is needed to correct inaccuracies in the emergency preparedness information approved in the early site permit; or

(v) Any significant environmental issue not considered which is material to the site or the design to the extent that it differs from those discussed or it reflects significant new information in addition to that discussed in the final environmental impact statement prepared by the Commission in connection with the early site permits.

(2) Any person may file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit should be modified, or that the permit should be suspended or revoked. The petition will be considered in accordance with § 2.206 of this chapter. Before construction commences, the Commission shall consider the petition and determine whether any immediate action is required. If the petition is granted, an appropriate order will be issued. Construction under the construction permit or combined license will not be affected by the granting of the petition unless the order is made immediately effective. Any change required by the Commission in response to the petition must meet the requirements of paragraph (a)(1) of this section.

(d) *Variances.* An applicant for a construction permit, operating license, or combined license referencing an early site permit may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. A variance will not be issued once the construction permit, operating license, or combined license is issued.

(e) *Information requests.* Except for information requests seeking to verify compliance with the current licensing basis of the early site permit, information requests to the holder of an early site permit must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f), and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

Subpart B – Standard Design Certifications

§ 52.41 Scope of subpart.

(a) This subpart sets forth the requirements and procedures applicable to Commission issuance of rules granting standard design certification for nuclear power facilities separate from the filing of an application for a construction permit or combined license for such a facility.

(b)(1) Any person may seek a standard design certification for an essentially complete nuclear power plant design which is an evolutionary change from light water reactor designs of plants which have been licensed and in commercial operation before April 18, 1989.

(2) Any person may also seek a standard design certification for a nuclear power plant design which differs significantly from the light water reactor designs described in

paragraph (b)(1) of this section or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions.

§ 52.43 Relationship to other subparts.

(a) This subpart applies to a person that requests a standard design certification from the NRC separately from an application for a combined license filed under subpart C of this part for a nuclear power facility. An applicant for a combined license may reference a standard design certification.

(b) Subpart E of this part governs the NRC staff review and approval of a final standard design. Subpart E may be used independently of the provisions in this subpart.

(c) Subpart F of this part governs the issuance of licenses to manufacture nuclear power reactors to be installed and operated at sites not identified in the manufacturing license application. Subpart F may be used independently of the provisions in this subpart.

§ 52.45 Filing of applications.

(a) An application for design certification may be filed notwithstanding the fact that an application for a construction permit or combined license for such a facility has not been filed.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and §§ 2.811 through 2.819 of this chapter.

(c) The fees associated with the review of an application for the initial issuance or renewal of a standard design certification are set forth in 10 CFR part 170.

§ 52.46 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (c) and (j).

§ 52.47 Contents of applications; technical information.

The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to

the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design certification must include performance requirements and design information sufficiently detailed to permit the preparation of acceptance and inspection requirements by the NRC, and procurement specifications and construction and installation specifications by an applicant. The Commission will require, before design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination.

(a) The application must contain a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and must include the following information:

(1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(2) A description and analysis of the structures, systems, and components (SSCs) of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which these requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that the standard plant will reflect through its design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The description shall be sufficient to permit understanding of the system designs and their relationship to the safety evaluations. Such items as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems,

radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

- (i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;
- (ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;
- (iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials; and
- (iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release³ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

³The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

(A) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem⁴ total effective dose equivalent (TEDE);

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(3) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to 10 CFR part 50, general design criteria (GDC), establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria;

(iii) Information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with an adequate margin for safety;

⁴A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. This dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

(4) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of emergency core cooling system (ECCS) cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter;

(5) A description and analysis of the fire protection design features for the standard plant necessary to comply with 10 CFR part 50, appendix A, GDC 3;

(6) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in 10 CFR 50.60 and 50.61;

(7) An analysis and description of the equipment and systems for combustible gas control as required by 10 CFR 50.44;

(8) A coping analysis, and any design features necessary to address station blackout, as required by 10 CFR 50.63;

(9) A description of the kinds and quantities of radioactive materials expected to be produced and used in the construction and operation and the design features for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR part 20;

(10) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e);

(11) The information on electric equipment important to safety that is required by 10 CFR 50.49(d);

(12) - (15) **[RESERVED]**

(16) The information necessary to demonstrate that SSCs important to safety comply with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(17) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(18) The information necessary to demonstrate technical resolutions of those unresolved safety issues and medium- and high-priority generic safety issues that are identified in the version of NUREG-0933 current on the date 6 months before the docket date of the application and that are technically relevant to the standard plant design;

(19) The information necessary to demonstrate how operating experience insights from generic letters and bulletins issued up to six months before the docket date of the application, or comparable international operating experience, has been incorporated into the plant design;

(20) A description and analysis of design features for the prevention and mitigation of severe accidents (core-melt accidents), including challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen detonation, and containment bypass;

(21) A description of the quality assurance program to be applied to the design of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 will be satisfied;

(22) Proposed technical specifications prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

(23) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(24) A description of the design features that will provide physical protection of the standard plant design in accordance with the requirements of 10 CFR part 73;

(25) A representative conceptual design for those portions of the standard plant for which the application does not seek certification, to aid the NRC in its review of the final safety analysis and probabilistic risk assessment, and to permit assessment of the adequacy of the interface requirements in paragraph (b)(3) of this section;

(26) An evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for a facility and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP was issued to establish criteria that the NRC staff intends to use in evaluating whether an applicant meets the Commission's regulations. The SRP is not a substitute for the regulations, and compliance is not a requirement; and

(27) The NRC staff will advise the applicant on whether any technical information beyond that required by this section must be submitted.

(b) The application must also contain:

(1) A design-specific probabilistic risk assessment (PRA). The design-specific PRA shall be full scope and account for all operating modes and initiating events;

(2) The proposed inspections, tests, analyses, and acceptance criteria (ITAAC) that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a plant that incorporates the design certification is built and will operate in accordance with the design certification, the provisions of the Act, and the Commission's regulations;

(3) The interface requirements to be met by those portions of the plant for which the application does not seek certification. These requirements must be sufficiently detailed to allow completion of the final safety analysis and design-specific PRA required by this section;

(4) Justification that compliance with the interface requirements of paragraph (b)(3) of this section is verifiable through inspection, testing (either in the plant or elsewhere), or analysis. The method to be used for verification of interface requirements must be included as part of the proposed ITAAC required by paragraph (b)(2) of this section; and

(5) An evaluation of severe accident mitigation design alternatives to the plant design under 10 CFR 51.30, and a description of how cost-beneficial design alternatives are included in the standard plant design.

(c) This paragraph applies, according to its provisions, to particular applications:

(1) An application for certification of a nuclear power reactor design that is an evolutionary change from light-water reactor designs of plants that have been licensed and in commercial operation before April 18, 1989, must provide an essentially complete nuclear power plant design except for site-specific elements such as the service water intake structure and the ultimate heat sink;

(2) An application for certification of a nuclear power reactor design that differs significantly from the light-water reactor designs described in paragraph (c)(1) of this section or

uses simplified, inherent, passive, or other innovative means to accomplish its safety functions must provide an essentially complete nuclear power reactor design except for site-specific elements such as the service water intake structure and the ultimate heat sink and must meet the requirements of 10 CFR 50.43(e); and

(3) An application for certification of a modular nuclear power reactor design must describe the various options for the configuration of the plant and site, including variations in, or sharing of, common systems, interface requirements, and system interactions. The final safety analysis and the PRA must also account for differences among the various options, including any restrictions that will be necessary during the construction and startup of a given module to ensure the safe operation of any module already operating.

§ 52.48 Standards for review of applications.

Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR parts 20, 50 and its appendices, 51, 73, and 100.

§ 52.51 Administrative review of applications.

(a) A standard design certification is a rule that will be issued in accordance with the provisions of subpart H of 10 CFR part 2, as supplemented by the provisions of this section. The Commission shall initiate the rulemaking after an application has been filed under § 52.45 and shall specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the *Federal Register* must provide an opportunity for the submission of comments on the proposed design certification rule. If, at the time a proposed design certification rule is published in the *Federal Register* under § 52.51(a), the Commission decides that a legislative hearing should be held, the information required by 10 CFR 2.1502(c) must be included in the *Federal Register* document for the proposed design certification

(b) Following the submission of comments on the proposed design certification rule, the Commission may, at its discretion, hold a legislative hearing under the procedures in subpart O

of part 2 of this chapter. The Commission shall publish a document in the *Federal Register* of its decision to hold a legislative hearing. The document shall contain the information specified in paragraph (c) of this section, and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(c) Notwithstanding anything in 10 CFR 2.390 to the contrary, proprietary information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for licenses, provided that the design certification shall be published in chapter I of this title.

§ 52.53 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.54 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 52.51 on an application for a standard design certification and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 52.53, the Commission may issue a standard design certification in the form of a rule for the design which is the subject of the application, if the Commission determines that:

(1) The application meets the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the standard design conforms with the provisions of the Act, and the Commission's regulations;

(4) The applicant is technically qualified;

(5) The proposed inspections, tests, analyses, and acceptance criteria are necessary and sufficient, within the scope of the standard design, to provide reasonable assurance that, if

the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will be operated in accordance with the design certification, the provisions of the Act, and the Commission's regulations;

(6) Issuance of the standard design certification will not be inimical to the common defense and security or to the health and safety of the public;

(7) The findings required by subpart A of part 51 of this chapter have been made; and

(8) The applicant has implemented the quality assurance program described or referenced in the safety analysis report.

(b) The design certification rule shall specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.

(c) After the Commission has adopted a final standard design certification rule, the applicant will not permit any individual to have access to or any facility to possess restricted data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95.

§ 52.55 Duration of certification.

(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for fifteen years from the date of issuance.

(b) A standard design certification continues to be valid beyond the date of expiration in any proceeding on an application for a combined license or an operating license that references the standard design certification and is docketed either before the date of expiration of the certification, or, if a timely application for renewal of the certification has been filed, before the Commission has determined whether to renew the certification. A design certification also continues to be valid beyond the date of expiration in any hearing held under § 52.103 before operation begins under a combined license that references the design certification.

(c) An applicant for a construction permit or a combined license may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 52.57 Application for renewal.

(a) Not less than 12 nor more than 36 months before the expiration of the initial 15-year period, or any later renewal period, any person may apply for renewal of the certification. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application. The Commission will require, before renewal of certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if this information is necessary for the Commission to make its safety determination. Notice and comment procedures must be used for a rulemaking proceeding on the application for renewal. The Commission, in its discretion, may require the use of additional procedures in individual renewal proceedings.

(b) A design certification, either original or renewed, for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in certain proceedings, in accordance with the provisions of § 52.55.

(c) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.59.

§ 52.59 Criteria for renewal.

(a) The Commission shall issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the

Atomic Energy Act and the Commission's regulations applicable and in effect at the time the certification was issued.

(b) The Commission may impose other requirements if it determines that:

(1) They are necessary for adequate protection to public health and safety or common defense and security;

(2) They are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the design certification was issued; or

(3) There is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementing those requirements are justified in view of this increased protection.

(c) In addition, the applicant for renewal may request an amendment to the design certification. The Commission shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act and the Commission's regulations in effect at the time of renewal. If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification must be filed in accordance with this subpart.

(d) Denial of renewal does not bar the applicant, or another applicant, from filing a new application for certification of the design, which proposes design changes that correct the deficiencies cited in the denial of the renewal.

§ 52.61 Duration of renewal.

Each renewal of certification for a standard design will be for not less than 10, nor more than 15 years.

§ 52.63 Finality of standard design certifications.

(a)(1) Notwithstanding any provision in 10 CFR 50.109, while a standard design certification rule is in effect under §§ 52.55 or 52.61, the Commission may not modify, rescind, or impose new requirements on the certification information, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that the change:

(i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;

(ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security; or

(iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security.

(2) The rulemaking procedures must provide for notice and opportunity for public comment.

(3) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant by action taken under paragraphs (a)(4) or (b)(1) of this section.

(4) The Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing the design certification rule if that part was approved in the design certification while a design certification rule is in effect under § 52.55 or § 52.61, unless:

(i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security; and

(ii) Special circumstances as defined in 10 CFR 52.7 are present. In addition to the factors listed in § 52.7, the Commission shall consider whether the special circumstances which § 52.7 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.

(5) Except as provided in 10 CFR 2.335, in making the findings required for issuance of a combined license or operating license, or for any hearing under § 52.103, the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b)(1) An applicant or licensee who references a standard design certification rule may request an exemption from one or more elements of the design certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 52.7. In addition to the factors listed in § 52.7, the Commission shall consider whether the special circumstances that § 52.7 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an exemption on request of an applicant must be subject to litigation in the same manner as other issues in the operating license or combined license hearing.

(2) Subject to § 50.59, a licensee who references a standard design certification rule may make changes to the design of the nuclear power facility, without prior Commission approval, unless the proposed change involves a change to the design as described in the rule certifying the design. The licensee shall maintain records of all changes to the facility and these records must be maintained and available for audit until the date of termination of the license.

(c) The Commission will require, before granting a construction permit, combined license, or operating license which references a standard design certification rule, that information normally contained in certain procurement specifications and construction and

installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

Subpart C – Combined Licenses

§ 52.71 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of combined licenses for nuclear power facilities.

§ 52.73 Relationship to other subparts.

(a) An application for a combined license under this subpart may, but need not, reference a standard design certification, standard design approval, or manufacturing license issued under subparts B, E, or F of this part, respectively, or an early site permit issued under subpart A of this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a design certification is qualified to supply a design, the Commission will entertain an application for a combined license that references a standard design certification issued under subpart B of this part only if the entity that sponsored and obtained the certification supplies the design for the applicant's use.

(b) The Commission will require, before granting a combined license that references a standard design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information.

§ 52.75 Filing of applications.

(a) Any person except one excluded by 10 CFR 50.38 may file an application for a combined license for a nuclear power facility with the Director of Nuclear Reactor Regulation.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR part 170.

§ 52.77 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33. The application must also state the earliest and latest dates for completion of construction.

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) The application must contain a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components of the facility as a whole. The final safety analysis report shall include the following information, at a level of information sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license:

(1)(i) The boundaries of the site;

(ii) The proposed general location of each facility on the site;

(iii) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated;

(iv) The location and description of any nearby industrial, military, or transportation facilities and routes;

(v) The existing and projected future population profile of the area surrounding the site;

(vi) A description and safety assessment of the site on which the facility is to be located.

The assessment must contain an analysis and evaluation of the major structures, systems, and

components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(vi)(A) and (a)(1)(vi)(B) of this section. In performing this assessment, an applicant shall assume a fission product release⁵ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem⁶ total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release

⁵The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

⁶A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

(during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE; and

(2) A description and analysis of the structures, systems, and components of the facility with emphasis upon performance requirements, the bases, with technical justification therefor, upon which these requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that reactors will reflect through their design, construction and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The descriptions shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations. Items as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics and proposed operation will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials;

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to

mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release⁷ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated;

(3) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter;

(4) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to part 50 of this chapter, "General Design Criteria for Nuclear Power Plants," establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria;

(iii) Information relative to materials of construction, arrangement, and dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with adequate margin for safety.

(5) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal

⁷The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter;

(6) A description and analysis of the fire protection design features for the reactor necessary to comply with 10 CFR part 50, appendix A, GDC 3, and § 50.48 of this chapter;

(7) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in §§ 50.60, and 50.61 (b)(1) and (b)(2) of this chapter;

(8) The analyses and the descriptions of the equipment and systems required by § 50.44 of this chapter for combustible gas control;

(9) The coping analyses required, and any necessary design features necessary to address station blackout, as described in § 50.63 of this chapter;

(10) A description of the program required by § 50.49(a) of this chapter for the environmental qualification of electric equipment important to safety and the list of electric equipment important to safety that is required by 10 CFR 50.49(d);

(11) A description of the program(s) necessary to ensure that the systems and components meet the requirements of the ASME Boiler and Pressure Vessel Code in accordance with § 50.55a of this chapter;

(12) A description of the primary containment leakage rate testing program necessary to ensure that the containment meets the requirements of Appendix J to 10 CFR part 50;

(13) A description of the reactor vessel material surveillance program required by Appendix H to 10 CFR Part 50;

(14) A description of the operator training program necessary to meet the requirements of 10 CFR part 55;

(15) A description of the program for monitoring the effectiveness of maintenance necessary to meet the requirements of § 50.65 of this chapter;

(16) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, as described in § 50.34a(d) of this chapter;

(17) The information with respect to compliance with technically relevant positions of the Three Mile Island requirements in § 50.34(f) of this chapter, with the exception of §§ 50.34(f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(18) If the applicant seeks to use risk-informed treatment of SSCs in accordance with the information required by § 50.69(b)(2) of this chapter;

(19) Information necessary to demonstrate that the SSCs important to safety comply with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(20) Proposed technical resolutions of those unresolved safety issues and medium- and high-priority generic safety issues that are identified in the version of NUREG-0933 current on the date 6 months before application and that are technically relevant to the design;

(21) Emergency plans complying with the requirements of § 50.47 of this chapter, and 10 CFR part 50, appendix E;

(22)(i) All emergency plan certifications that have been obtained from the State and local governmental agencies with emergency planning responsibilities must state that:

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency;

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(23) If the applicant wishes to be able to perform the activities at the site allowed by 10 CFR 50.10(e) before issuance of the combined license, the applicant must identify and describe the activities that are requested and propose a plan for redress of the site in the event that the activities are performed and either construction is abandoned or the combined license is revoked. The application must demonstrate that there is reasonable assurance that redress carried out under the plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws;

(24) If the application is for a nuclear power reactor design which differs significantly from light-water reactor designs that were licensed before 1997 or use simplified, inherent, passive, or other innovative means to accomplish their safety functions, the application must describe how the design meets the requirements in § 50.43(e) of this chapter;

(25) A description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50 sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 will be satisfied;

(26) The applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements for operation;

(27) Managerial and administrative controls to be used to assure safe operation.

Appendix B to 10 CFR part 50 sets forth the requirements for these controls for nuclear power plants. The information on the controls to be used for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 will be satisfied;

(28) Plans for preoperational testing and initial operations;

(29) Plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components;

(30) Proposed technical specifications prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

(31) For nuclear power plants to be operated on multi-unit sites, an evaluation of the potential hazards to the structures, systems, and components important to safety of operating units resulting from construction activities, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation are not exceeded as a result of construction activities at the multi-unit sites;

(32) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(33) A description of the training program required by § 50.120 of this chapter;

(34) A description and plans for implementation of an operator requalification program.

The operator requalification program must as a minimum, meet the requirements for those programs contained in § 55.59 of this chapter;

(35) A physical security plan, describing how the applicant will meet the requirements of 10 CFR part 73 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable;

(36)(A) A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license shall include the information contained in the applicant's safeguards contingency plan.⁸ (Implementing procedures required for this plan need not be submitted for approval.)

(B) Each applicant who prepares a physical security plan, a safeguards contingency plan, or a guard qualification and training plan, shall protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of § 73.21 of this chapter, as appropriate.

(37) The information which demonstrates how operating experience insights from generic letters and bulletins issued up to 6 months before the docket date of the application, or comparable international operating experience, has been incorporated into the plant design;

(38) A description and analysis of design features for the prevention and mitigation of severe accidents (core-melt accidents), including challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen detonation, and containment bypass;

(39) The earliest and latest dates for completion of the construction;

(40) **[RESERVED]**

(41) For applications for light-water cooled nuclear power plant combined licenses, an evaluation of the facility against the Standard Review Plan (SRP) in effect 6 months before the docket date of the application. The evaluation required by this section shall include an

⁸A physical security plan that contains all the information required in both §§ 73.55 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

identification and description of all differences in design features, analytical techniques and procedural measures proposed for a facility and those corresponding features, techniques and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP was issued to establish criteria that the NRC staff intends to use in evaluating whether an applicant/licensee meets the Commission's regulations. The SRP is not a substitute for the regulations, and compliance is not a requirement;

(42) The NRC staff will advise the applicant on whether any information beyond that required by this section must be submitted.

(b) If the application for a final safety analysis report references an early site permit, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the early site permit, but must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the final safety analysis report does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application shall include a request for a variance that complies with the requirements of §§ 52.39 and 52.93.

(3) The final safety analysis report must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the combined license.

(4) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the final safety analysis report must include any new or

additional information that updates and corrects the information that was provided under § 52.17(b), and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. If the proposed facility emergency plans incorporate existing emergency plans or major features of emergency plans, the application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute a decrease in effectiveness under § 50.54(q) of this chapter.

(5) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(22) of this section are not required.

(c) If the combined license application references a standard design approval, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the design approval, but must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval.

(2) The final safety analysis report must demonstrate that the interface requirements established for the design under § 52.137 have been met.

(3) The final safety analysis report must demonstrate that all terms and conditions that have been included in the final design approval will be satisfied by the date of issuance of the combined license.

(d) If the combined license application references a standard design certification, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the design certification, but must contain, in addition to

the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design certification.

(2) The final safety analysis report must demonstrate that the interface requirements established for the design under § 52.47 have been met.

(3) The final safety analysis report must demonstrate that all requirements and restrictions set forth in the referenced design certification rule must be satisfied by the date of issuance of the combined license.

(e) If the combined license application references the use of one or more manufactured nuclear power reactors licensed under subpart F of this part, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the manufacturing license, but must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site parameters for the manufactured reactor are bounded by the site where the manufactured reactor is to be installed and used.

(2) The final safety analysis report must demonstrate that the interface requirements established for the design have been met.

(3) The final safety analysis report must demonstrate that all terms and conditions that have been included in the manufacturing license will be satisfied by the date of issuance of the combined license.

§ 52.80 Contents of applications; additional technical information.

The application must contain:

(a) A full scope, plant-specific probabilistic risk assessment (PRA) that accounts for all operating modes and initiating events at the facility. If the application references a standard design certification or standard design approval, or if the application proposes to use a nuclear

power reactor manufactured under a manufacturing license under subpart F of this part, the plant-specific PRA must use the PRA for the design certification, design approval, or manufactured reactor, as applicable, and must be updated to account for site-specific design information and any design changes, departures, or variances.

(b) The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria which are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the combined license, the provisions of the Atomic Energy Act, and the NRC's regulations.

(1) If the application references an early site permit with ITAAC, the early site permit ITAAC must apply to those aspects of the combined license which are approved in the early site permit.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are approved in the design certification.

(3) If the application references an early site permit with ITAAC or a standard design certification or both, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 52.85 must indicate that the application includes this notification.

(c) A complete environmental report as required by 10 CFR 51.50(c).

§ 52.81 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR parts 20, 50, 51, 54, 55, 73, 100, and 140.

§ 52.83 Finality of referenced NRC approvals.

If the application for a combined license under this subpart references an early site permit, design certification rule, standard design approval, or manufacturing license, the scope and nature of matters resolved for the application and any combined license issued are governed by the relevant provisions addressing finality, including §§ 52.39, 52.63, 52.98, 52.145, and 52.171.

§ 52.85 Administrative review of applications; hearings.

A proceeding on a combined license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing. All hearings on combined licenses are governed by the procedures contained in 10 CFR part 2.

§ 52.87 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application that concern safety and shall apply the standards referenced in § 52.81, in accordance with the finality provisions in § 52.83.

§ 52.89 [RESERVED]

§ 52.91 Authorization to conduct site activities.

(a) If the application does not reference an early site permit which authorizes the applicant to perform site preparation activities, the applicant may not perform the site preparation activities allowed by 10 CFR 50.10(e)(1) without obtaining the separate authorization required by 10 CFR 50.10(e)(1). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by 10 CFR 50.10(e)(2) and has determined that there is reasonable assurance that

redress carried out under the site redress plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

(b) Authorization to conduct the activities described in 10 CFR 50.10(e)(3)(i) may be granted only after the presiding officer in the combined license proceeding makes the additional finding required by 10 CFR 50.10(e)(3)(ii).

(c) If, after an applicant for a combined license has performed the activities permitted by paragraph (a) of this section, the application for the license is withdrawn or denied, and the early site permit referenced by the application expires, then the applicant shall redress the site in accord with the terms of the site redress plan. If a use not envisaged in the redress plan is found for the site or parts before redress is complete, the applicant shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 52.93 Exemptions and variances.

(a) Applicants for a combined license under this subpart, or any amendment to a combined license, may include in the application a request for an exemption from one or more of the Commission's regulations.

(1) If the request is for an exemption from any part of a referenced design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced design certification rule, or with § 52.63 if there are no applicable exemption provisions in the referenced design certification rule.

(2) For all other requests for exemptions, the Commission may grant a request if it determines that the exemption complies with § 52.7.

(b) An applicant for a combined license who has filed an application referencing an early site permit issued under this subpart may include in the application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of

the permit. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit.

(c) Issuance of the variance is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

§ 52.97 Issuance of combined licenses.

(a)(1) After conducting a hearing in accordance with § 52.85 and receiving the report submitted by the ACRS, the Commission may issue a combined license if the Commission finds that:

(i) The applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations.

(iv) The applicant is technically and financially qualified to engage in the activities authorized; and

(v) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and

(vi) The findings required by subpart A of part 51 of this chapter have been made.

(2) The Commission may also find, at the time it issues the combined license, that certain acceptance criteria in one or more of the inspections, tests, analyses, and acceptance criteria (ITAAC) in a referenced early site permit or standard design certification have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance criteria will be deemed to be excluded from the combined license, and findings under § 52.103(g) with respect to those acceptance criteria are unnecessary.

(b) The Commission shall identify within the combined license the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations.

(c) A combined license shall contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

§ 52.98 Finality of combined licenses; information requests.

(a) After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of § 52.103 or § 50.109 of this chapter, as applicable.

(b) If the combined license does not reference a design certification or a reactor manufactured under a subpart F of this part manufacturing license, then a licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) under the applicable change processes in 10 CFR part 50 (e.g., § 50.54, § 50.59, or § 50.90).

(c) If the combined license references a certified design, then—

(1) Changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule; and

(2) Changes that are not within the scope of the referenced design certification rule are subject to the applicable change processes in 10 CFR part 50, unless they also involve changes

to or noncompliance with information within the scope of the referenced design certification rule. In these cases, the applicable provisions of this section and the design certification rule apply.

(d) If the combined license references a reactor manufactured under a subpart F of this part manufacturing license, then-

(1) Changes to or variances from information within the scope of the manufactured reactor's design are subject to the change processes in § 52.171; and

(2) Changes that are not within the scope of the manufactured reactor's design are subject to the applicable change processes in 10 CFR part 50.

(e) The Commission may issue and make immediately effective any amendment to a combined license upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed in accordance with the procedures specified in 10 CFR 50.91.

(f) Any modification to, addition to, or deletion from the terms and conditions of a combined license, including any modification to, addition to, or deletion from the inspections, tests, analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

(g) Except for information sought to verify licensee compliance with the current licensing basis for that facility, information requests to the holder of a combined license must be evaluated before issuance to ensure that the burden to be imposed on the licensee is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.99 Inspection during construction.

(a) Holders of combined licenses shall comply with the provisions of 10 CFR 50.70 and 50.71.

(b) With respect to activities subject to an ITAAC, an applicant for a combined license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and pre-operational activities, even though the NRC may not have found that any particular ITAAC has been met.

(c) The licensee shall notify the NRC that the inspections, tests, or analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met. For those inspections, tests, or analyses that are completed within 180 days prior to the scheduled date for initial loading of fuel, the licensee shall notify the NRC within 10 days of the successful completion of ITAAC.

(d)(1) In the event that an activity is subject to an ITAAC derived from a referenced early site permit or standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC, request a variance from the early site permit ITAAC, or request an exemption from the standard design certification ITAAC, as applicable. A request for a variance or an exemption must also be accompanied by a request for a license amendment under § 52.98(c).

(2) In the event that an activity is subject to an ITAAC not derived from a referenced early site permit or standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under § 52.98(c).

(e) The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. At appropriate intervals, the NRC shall publish notices in the *Federal*

Register of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

§ 52.103 Operation under a combined license.

(a) Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a combined license under subpart C of this part, the Commission shall publish notice of intended operation in the *Federal Register*. The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the combined license, except that a hearing shall not be granted for those ITAAC which the Commission found were met under § 52.97(a)(2).

(b) A request for hearing under paragraph (a) of this section must show, *prima facie*, that—

(1) One or more of the acceptance criteria of the ITAAC in the combined license have not been, or will not be met; and

(2) The specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(c) After receiving a request for a hearing, the Commission expeditiously shall either deny or grant the request. If the request is granted, the Commission shall determine, after considering petitioners' *prima facie* showing and any answers thereto, whether during a period of interim operation, there will be reasonable assurance of adequate protection of the public health and safety. If the Commission determines that there is reasonable assurance, it shall allow operation during an interim period under the combined license.

(d) The Commission shall determine appropriate hearing procedures in accordance with 10 CFR part 2 for any hearing under paragraph (a) of this section.

(e) The Commission shall, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or by the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the combined license will be processed as a request for action in accordance with 10 CFR 2.206. The petitioner shall file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the Commission shall determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the combined license will not be affected by the granting of the petition unless the order is made immediately effective.

(g) The licensee shall not load fuel into the reactor and shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 52.97(a)(2). If the combined license is for a modular design, each reactor module may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the combined license, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (a) of this section, all ITAAC expire upon final Commission action in the proceeding. However, subsequent changes to the facility or procedures described in the final safety analysis report (as updated) must comply with the requirements in §§ 52.98(e) or (f), as applicable.

§ 52.104 Duration of combined license.

A combined license is issued for a specified period not to exceed 40 years from the date on which the Commission makes a finding that acceptance criteria are met under § 52.103(g) or allowing operation during an interim period under the combined license under § 52.103(c).

§ 52.105 Transfer of combined license.

A combined license may be transferred in accordance with § 50.80 of this chapter.

§ 52.107 Application for renewal.

The filing of an application for a renewed license must be in accordance with 10 CFR part 54.

§ 52.109 Continuation of combined license.

(a) Each combined license for a facility that has permanently ceased operations, continues in effect beyond the expiration date to authorize ownership and possession of the production or utilization facility, until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness the licensee shall—

(1) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(2) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the combined license for the facility.

§ 52.110 Termination of license.

(a)(1) When a licensee has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 52.3(b)(8);

(2) Once fuel has been permanently removed from the reactor vessel, the licensee shall submit a written certification to the NRC that meets the requirements of § 52.3(b)(9); and

(3) For licensees whose licenses have been permanently modified to allow possession but not operation of the facility, before [insert the effective date of this rule], the certification required in paragraph (a)(1) of this section shall be deemed to have been submitted.

(b) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the 10 CFR part 52 license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel.

(c) Decommissioning will be completed within 60 years of permanent cessation of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site-specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.

(d)(1) Before or within 2 years following permanent cessation of operations, the licensee shall submit a post-shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The report must include a description of the planned decommissioning activities along with a schedule for their accomplishment, an estimate of expected costs, and a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements.

(2) The NRC shall notice receipt of the PSDAR and make the PSDAR available for public comment. The NRC shall also schedule a public meeting in the vicinity of the licensee's

facility upon receipt of the PSDAR. The NRC shall publish a document in the *Federal Register* and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time and location of the meeting, along with a brief description of the purpose of the meeting.

(e) Licensees shall not perform any major decommissioning activities, as defined in § 50.2 of this chapter, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel, as required under § 52.110(a)(1), have been submitted.

(f) Licensees shall not perform any decommissioning activities, as defined in § 52.1, that—

- (1) Foreclose release of the site for possible unrestricted use;
- (2) Result in significant environmental impacts not previously reviewed; or
- (3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(g) In taking actions permitted under § 50.59 of this chapter following submittal of the PSDAR, the licensee shall notify the NRC in writing and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that significantly increase the decommissioning cost.

(h)(1) Decommissioning trust funds may be used by licensees if—

- (i) The withdrawals are for expenses for legitimate decommissioning activities consistent with the definition of decommissioning in § 52.1;
- (ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise and;

(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(2) Initially, 3 percent of the generic amount specified in § 50.75 of this chapter may be used for decommissioning planning. For licensees that have submitted the certifications required under § 52.110(a) and commencing 90 days after the NRC has received the PSDAR, an additional 20 percent may be used. A site-specific decommissioning cost estimate must be submitted to the NRC before the licensee using any funding in excess of these amounts.

(3) Within 2 years following permanent cessation of operations, if not already submitted, the licensee shall submit a site-specific decommissioning cost estimate.

(4) For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee shall provide a means of adjusting cost estimates and associated funding levels over the storage or surveillance period.

(i) All power reactor licensees must submit an application for termination of license. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(1) The license termination plan must be a supplement to the FSAR or equivalent and must be submitted at least 2 years before termination of the license date.

(2) The license termination plan must include—

(i) A site characterization;

(ii) Identification of remaining dismantlement activities;

(iii) Plans for site remediation;

(iv) Detailed plans for the final radiation survey;

(v) A description of the end use of the site, if restricted;

(vi) An updated site-specific estimate of remaining decommissioning costs;

(vii) A supplement to the environmental report, under § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

(viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.

(3) The NRC shall notice receipt of the license termination plan and make the license termination plan available for public comment. The NRC shall also schedule a public meeting in the vicinity of the licensee's facility upon receipt of the license termination plan. The NRC shall publish a document in the *Federal Register* and in a forum, such as local newspapers, which is readily accessible to individuals in the vicinity of the site, announcing the date, time and location of the meeting, along with a brief description of the purpose of the meeting.

(j) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission shall approve the plan, by license amendment, subject to terms and conditions as it deems appropriate and necessary and authorize implementation of the license termination plan.

(k) The Commission shall terminate the license if it determines that—

(1) The remaining dismantlement has been performed in accordance with the approved license termination plan; and

(2) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in subpart E to 10 CFR part 20.

(l) For a facility that has permanently ceased operation before the expiration of its license, the collection period for any shortfall of funds will be determined, upon application by the licensee, on a case-by-case basis taking into account the specific financial situation of each licensee.

Subpart D – RESERVED

Subpart E - Standard Design Approvals

§ 52.131 Scope of subpart.

This subpart sets out procedures for the filing, NRC staff review, and referral to the Advisory Committee on Reactor Safeguards of standard designs for a nuclear power reactor of the type described in § 50.22 of this chapter or major portions thereof.

§ 52.133 Relationship to other subparts.

(a) This subpart applies to a person that requests a standard design approval from the NRC staff separately from an application for a construction permit filed under 10 CFR part 50 or a combined license filed under subpart C of this part. An applicant for a construction permit or combined license may reference a standard design approval.

(b) Subpart B of this part governs the certification by rulemaking of the design of a nuclear power plant. Subpart B may be used independently of the provisions in this subpart.

(c) Subpart F of this part governs the issuance of licenses to manufacture nuclear power reactors to be installed and operated at sites not identified in the manufacturing license application. Subpart F of this part may be used independently of the provisions in this subpart.

§ 52.135 Filing of applications.

(a) Any person may submit a proposed standard design for a nuclear power reactor of the type described in 10 CFR 50.22 to the NRC staff for its review. The submittal may consist of either the final design for the entire facility or the final design of major portions thereof.

(b) The submittal for review of the proposed standard design must be made in the same manner and in the same number of copies as provided in 10 CFR 50.30 and 52.3 for license applications.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR part 170.

§ 52.136 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (d) and (j).

§ 52.137 Contents of applications; technical information.

If the applicant seeks review of a major portion of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought.

(a) The application must contain a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and must include the following information:

(1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(2) A description and analysis of the SSCs of the facility, with emphasis upon performance requirements, the bases, with technical justification, upon which the requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that the standard plant will reflect through its design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The description shall be sufficient to permit understanding of the system designs and their relationship to the safety evaluations. Items

such as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

(i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials; and

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release⁹ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site

⁹The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem¹⁰ total effective dose equivalent (TEDE); and

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(3) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to 10 CFR part 50, general design criteria (GDC), establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria; and

¹⁰A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

(iii) Information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with adequate margin for safety;

(4) An analysis and evaluation of the design and performance of SSC with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of 10 CFR 50.46 and 50.46a;

(5) A description and analysis of the fire protection design features for the standard plant necessary to comply with 10 CFR part 50, appendix A, GDC 3;

(6) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in 10 CFR 50.60 and 50.61;

(7) An analysis and description of the equipment and systems for combustible gas control as required by 10 CFR 50.44;

(8) A coping analysis, and any design features necessary to address station blackout, as required by 10 CFR 50.63;

(9) A description of the kinds and quantities of radioactive materials expected to be produced and used in the construction and operation and the design features for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR part 20;

(10) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e);

(11) The information on electric equipment important to safety that is required by 10 CFR 50.49(d);

(12) - (15) **[RESERVED]**

(16) The information necessary to demonstrate that SSCs important to safety comply with the earthquake engineering criteria in 10 CFR part 50, appendix S;

(17) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v) of 10 CFR 50.34(f);

(18) The information necessary to demonstrate technical resolutions of those unresolved safety issues and medium- and high-priority generic safety issues that are identified in the version of NUREG-0933 current on the date 6 months before the docket date of the application and that are technically relevant to the standard plant design;

(19) The information necessary to demonstrate how operating experience insights from generic letters and bulletins issued up to 6 months before the docket date of the application, or comparable international operating experience, has been incorporated into the plant design;

(20) A description and analysis of design features for the prevention and mitigation of severe accidents (core-melt accidents), including challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen detonation, and containment bypass;

(21) A description of the quality assurance program to be applied to the design of the SSCs of the facility. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance

programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 will be satisfied;

(22) The information pertaining to design features that affect plans for coping with emergencies in the operation of the reactor facility or a major portion thereof;

(23) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(24) A description of the design features that will provide physical protection of the standard plant design in accordance with the requirements of 10 CFR part 73;

(25) **[RESERVED]**;

(26) An evaluation of the standard design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for a facility and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the alternative proposed provides an acceptable method of complying with Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP was issued to establish criteria that the NRC staff intends to use in evaluating whether an applicant meets the Commission's regulations. The SRP is not a substitute for the regulations, and compliance is not a requirement; and

(27) The NRC staff will advise the applicant on whether any technical information beyond that required by this section must be submitted.

(b) The application must also contain:

(1) A design-specific probabilistic risk assessment (PRA). The design-specific PRA shall be full scope and account for all operating modes and initiating events;

(2) **[RESERVED]**;

(3) A description, analysis, and evaluation of the interfaces between the standard design and the balance of the nuclear power plant.

(c) An application for approval of a standard design, which differs significantly from the light-water reactor designs of plants that have been licensed and in commercial operation before April 18, 1989, or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions, must meet the requirements of 10 CFR 50.43(e).

§ 52.139 Standards for review of applications.

Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR parts 20, 50 and its appendices, and 10 CFR parts 73 and 100.

§ 52.141 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.143 Staff approval of design.

Upon completion of its review of a submittal under this subpart and receipt of a report by the Advisory Committee on Reactor Safeguards under § 52.141 of this subpart, the NRC staff shall publish a determination in the *Federal Register* as to whether or not the design is acceptable, subject to appropriate terms and conditions, and make an analysis of the design in the form of a report available at the NRC Web site, <http://www.nrc.gov>.

§ 52.145 Finality of standard design approvals; information requests.

(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their review of any individual facility license application that incorporates by reference a standard design approved in accordance with this paragraph unless there exists significant new information that substantially affects the earlier determination or other good cause.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under part 2 of this chapter.

(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.147 Duration of design approval.

A standard design approval issued under this subpart is valid for 15 years from the date of issuance and may not be renewed. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a construction permit, combined license, or an operating license which references the standard design approval and is docketed before the date of expiration of the design approval.

Subpart F – Manufacturing Licenses

§ 52.151 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of a license authorizing manufacture of nuclear power reactors to be installed at sites not identified in the manufacturing license application.

§ 52.153 Relationship to other subparts.

(a) A nuclear power reactor manufactured under a manufacturing license issued under this subpart may only be transported to and installed at a site for which either a construction

permit under part 50 of this chapter or a combined license under subpart C of this part has been issued.

(b) Subpart B of this part governs the certification by rulemaking of the design of standard nuclear power facilities. Subpart E of this part governs the NRC staff review and approval of standard designs for a nuclear power facility. A manufacturing license applicant may reference a standard design certification, or a preliminary or final standard design approval in its application. These subparts may also be used independently of the provisions in this subpart.

§ 52.155 Filing of applications.

(a) Any person, except one excluded by 10 CFR 50.38, may file an application for a manufacturing license under his subpart with the Director of Nuclear Reactor Regulation.

(b) The application must comply with the applicable filing requirements of §§ 52.3 and 50.30 of this chapter.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR part 170.

52.156 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33(a) through (d), (j), and 50.33a.

§ 52.157 Contents of applications; technical information in final safety analysis report.

The application must contain a final safety analysis report containing the information set forth below, with a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that the manufacturing conforms to the design and to reach a final conclusion on all safety questions associated with the design, permit the preparation of construction and installation specifications by an applicant who seeks to use the

manufactured reactor, and permit the preparation of acceptance and inspection requirements by the NRC:

(a) The principal design criteria for the reactor to be manufactured. Appendix A of 10 CFR part 50, "General Design Criteria for Nuclear Power Plants," establishes minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(b) The design bases and the relation of the design bases to the principal design criteria;

(c) A description and analysis of the structures, systems, and components of the reactor to be manufactured, with emphasis upon the materials of manufacture, performance requirements, the bases, with technical justification therefor, upon which the performance requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations. Items such as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:

(i) Intended use of the manufactured reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;

(ii) The extent to which generally accepted engineering standards are applied to the design of the reactor; and

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials;

(d) The safety features that are to be engineered into the reactor and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to reactor design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release¹¹ from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(i) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem¹² total effective dose equivalent (TEDE);

¹¹The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release into the containment of appreciable quantities of fission products.

¹²A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of

(ii) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE; and

(iii) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter.

(e) Information necessary to establish that the design of the reactor to be manufactured complies with the technical requirements in part 50 of this chapter, including:

(1) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 and 50.46a of this chapter;

(2) A description and analysis of the fire protection design features for the reactor necessary to comply with GDC 3 and § 50.48 of this chapter;

(3) A description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in §§ 50.60 and 50.61 of this chapter;

public exposure to radiation, in the event of an accident.

(4) The analyses and the descriptions of the equipment and systems required by § 50.44 of this chapter for combustible gas control;

(5) The coping analyses required, and any design features necessary to address station blackout, as described in § 50.63 of this chapter;

(6) The information on electric equipment important to safety that is required by 10 CFR 50.49(d);

(7) - (10) **[RESERVED]**

(11) The information with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, as described in § 50.34a(e) of this chapter;

(12) The information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in § 50.34(f) of this chapter, except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v);

(13) If the applicant seeks to use risk-informed treatment of SSCs in accordance with the information required by § 50.69(b)(2) of this chapter;

(14) The earthquake engineering criteria in appendix S to 10 CFR part 50;

(15) Information sufficient to demonstrate compliance with the applicable requirements regarding testing, analysis, and prototypes as set forth in § 50.43(e) of this chapter;

(16) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter;

(17) A description of the quality assurance program to be applied to the design and manufacture of the structures, systems, and components of the reactor. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The

description of the quality assurance program must include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 will be satisfied; and

(18) Proposed technical specifications applicable to the reactor being manufactured, prepared in accordance with the requirements of §§ 50.36 and 50.36a of this chapter;

(f) The site parameters postulated for the design, and an analysis and evaluation of the reactor design in terms of those site parameters;

(g) The interface requirements between the manufactured reactor and the remaining portions of the nuclear power plant. These requirements must be sufficiently detailed to allow for completion of the final safety analysis and probabilistic risk assessment required by § 52.158(a);

(h) Justification that compliance with the interface requirements of paragraph (a)(18) of this section is verifiable through inspection, testing (either in the plant or elsewhere), or analysis;

(i) A representative conceptual design for a nuclear power facility using the manufactured reactor, to aid the NRC in its review of the final safety analysis required by this section and the probabilistic risk assessment required by § 52.158(a), and to permit assessment of the adequacy of the interface requirements in paragraph (g) of this section;

(j) A description and analysis of design features for the prevention and mitigation of severe accidents (core-melt accidents), including challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen detonation, and containment bypass;

(k) RESERVED;

(l) If the reactor is to be used in modular plant design, the various options for the configuration of the plant and site, including variations in, or sharing of, common systems, interface requirements, and system interactions must be described. The final safety analysis and the probabilistic risk assessment must account for differences among the various options,

including any restrictions which will be necessary during the construction and startup of a given module to ensure the safe operation of any module already operating;

(m) A description of the management plan for design and manufacturing activities, including:

(1) The organizational and management structure singularly responsible for direction of design and manufacture of the reactor;

(2) Technical resources directed by the applicant, and the qualifications requirements;

(3) Details of the interaction of design and manufacture within the applicant's organization and the manner by which the applicant will ensure close integration of the architect engineer and the nuclear steam supply vendor, as applicable;

(4) Proposed procedures governing the preparation of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and verifying the condition of the manufactured reactor upon receipt at the site; and

(5) The degree of top level management oversight and technical control to be exercised by the applicant during design and manufacture, including the preparation and implementation of procedures necessary to guide the effort;

(n) Necessary parameters to be used in developing plans for preoperational testing and initial operation;

(o) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority generic safety issues which are identified in the version of NUREG-0933 current on the date up to 6 months before application and which are technically relevant to the design;

(p) A description of how operating experience insights from generic letters and bulletins issued up to six months before the docket date of the application, or comparable international operating experience, has been incorporated into the design of the reactor to be manufactured;

(q) An evaluation of the site against applicable sections of the Standard Review Plan revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in analytical techniques and procedural measures proposed for a site and those corresponding techniques and measures given in the SRP acceptance criteria. Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The SRP was issued to establish criteria that the NRC staff intends to use in evaluating whether an applicant/licensee meets the Commission's regulations. The SRP is not a substitute for the regulations, and compliance is not a requirement; and

(r) The NRC staff shall advise the applicant if any information beyond that required by this section must be submitted.

§ 52.158 Contents of application; additional technical information.

The application must contain:

(a) *Probabilistic risk assessment (PRA)*. A full scope, design-specific probabilistic risk assessment (PRA) for the reactor. If the application references a certified design, the PRA for the certified design must be updated to reflect any additional portions of the reactor to be manufactured which are not within the scope of the certified design.

(b)(1) *Inspections, tests, analyses, and acceptance criteria (ITAAC)*. The proposed inspections, tests and analyses that the licensee who will be operating the reactor shall perform, and the acceptance criteria which are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met:

(i) The reactor has been manufactured in conformance with the manufacturing license; the provisions of the Atomic Energy Act, and the NRC's regulations; and

(ii) The reactor will operate in conformity with design characteristics in the manufacturing license, any license authorizing operation of the reactor as part of a nuclear power plant, the provisions of the Act, and the NRC's regulations.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 52.163 must indicate that the application includes this notification.

(c)(1) An environmental report as required by 10 CFR 51.54. The report must address the costs and benefits of severe accident mitigation design alternatives (SAMDA), and the bases for not incorporating SAMDA into the design of the reactor to be manufactured. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license. The related environmental assessment prepared by the NRC will be similarly directed.

(2) If the application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the reactor.

§ 52.159 Standards for review of application.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR parts 20, 50 and its appendices, 51, 73, and 100 and its appendices.

§ 52.161 [RESERVED]

§ 52.163 Administrative review of applications; hearings.

A proceeding on a manufacturing license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1)-(4) of this chapter, and the requirements for issuance of a notice of hearing in § 2.104 of this chapter, provided that the designated sections may not be construed to require that the environmental report or draft or final environmental impact statement include an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources. All hearings on manufacturing licenses are governed by the hearing procedures contained in 10 CFR part 2, subparts C, G and L.

§ 52.165 Referral to the Advisory Committee on Reactor Safeguards (ACRS).

The Commission shall refer a copy of the application to the ACRS. The ACRS shall report on those portions of the application which concern safety.

§ 52.167 Issuance of manufacturing license.

(a) After conducting a hearing in accordance with § 52.163 and receiving the report submitted by the ACRS, the Commission may issue a manufacturing license if the Commission finds that:

(1) Applicable standards and requirements of the Act and the Commission's regulations have been met;

(2) There is reasonable assurance that the reactor(s) will be manufactured, and can be transported, incorporated into a nuclear power plant, and operated in conformity with the manufacturing license, the provision of the Act, and the Commission's regulations;

(3) The proposed reactor(s) can be incorporated into a nuclear power plant and operated at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactor(s) without undue risk to the health and safety of the public;

(4) The applicant is technically qualified to design and manufacture the proposed nuclear power reactor(s);

(5) The proposed inspections, tests, analyses and acceptance criteria are necessary and sufficient, within the scope of the manufacturing license, to provide reasonable assurance that the manufactured reactor has been manufactured and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public; and

(7) The findings required by subpart A of part 51 of this chapter have been made.

(b) Each manufacturing license issued under this subpart shall specify:

(1) Terms and conditions as the Commission deems necessary and appropriate;

(2) Technical specifications for operation of the manufactured reactor, as the Commission deems necessary and appropriate;

(3) The number of nuclear power reactors authorized to be manufactured, and the latest date for completion of the manufacturing of all the reactors. The number of reactors to be specified in the manufacturing license may be no more than the number of reactors whose start of manufacture can practically begin within a 10-year period commencing on the date of issuance of the manufacturing license;

(4) Site parameters and design characteristics for the manufactured reactor; and

(5) The interface requirements to be met by the site-specific elements of the facility, such as the service water intake structure and the ultimate heat sink, not within the scope of the manufactured reactor.

(c) A holder of a manufacturing license may not transport or allow to be removed from the place of manufacture the manufactured reactor except to the site of a licensee with a either a construction permit under part 50 of this chapter or a combined license under subpart C of this part. The construction permit or combined license must authorize the construction of a nuclear power facility using the manufactured reactor(s).

§ 52.169 [Reserved]

§ 52.171 Finality of manufacturing licenses; information requests.

(a)(1) Notwithstanding any provision in 10 CFR 50.109, during the term of a manufacturing license the Commission may not modify, rescind, or impose new requirements on the design of the nuclear power reactor being manufactured, or the requirements for the manufacture of the nuclear power reactor, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

(2) Any modification to the design of a manufactured nuclear power reactor which is imposed by the Commission under paragraph (a)(1) of this section will be applied to all reactors manufactured under the license, including those that have already been transported and sited, except those reactors to which the modification has been rendered technically irrelevant by action taken under paragraph (b)(1) of this section.

(3) In making the findings required for issuance of a construction permit, operating license, combined license, and for any hearing under § 52.103, for which a nuclear power reactor manufactured under this subpart is referenced or used, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the manufacturing license, including the adequacy of design of the manufactured reactor and the environmental impacts of operation of the manufactured reactor.

(b)(1) The holder of a manufacturing license may not make changes to the design of the nuclear power reactor authorized to be manufactured without prior Commission approval. The request for a change to the design must be in the form of an application for a license amendment, and must meet the requirements of 10 CFR 50.90 through 50.92.

(2) An applicant or licensee who references or uses a nuclear power reactor manufactured under a manufacturing license under this subpart may request a variance from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the variance will comply with the requirements of 10 CFR 50.12(a), and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of a variance on request of an applicant must be subject to litigation in the same manner as other issues in the construction permit, operating license, or combined license hearing.

(c) Except for information requests seeking to verify compliance with the current licensing basis of either the manufacturing license or the manufactured reactor, information requests to the holder of a manufacturing license or an applicant or licensee using a manufactured reactor must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request.

§ 52.173 Duration of manufacturing license.

A manufacturing license issued under this subpart may be valid for not less than 5, nor more than 15 years from the date of issuance. A holder of a manufacturing license may not initiate the manufacture of a reactor less than 3 years before the expiration of the license even though a timely application for renewal has been filed with the NRC. Upon expiration of the manufacturing license, the manufacture of any uncompleted reactors must cease unless a timely application for renewal has been filed with the NRC.

§ 52.175 Transfer of manufacturing license.

A manufacturing license may be transferred in accordance with § 50.80 of this chapter.

§ 52.177 Application for renewal.

(a) Not less than 12 months, nor more than 5 years before the expiration of the manufacturing license, or any later renewal period, the holder of the manufacturing license may apply for a renewal of the license.

(b) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and 10 CFR 52.3 and 50.30.

(c) A manufacturing license, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has made a final determination on the renewal application, *provided, however*, that in accordance with § 52.173, the holder of a manufacturing license may not begin manufacture of a reactor less than 3 years before the expiration of the license.

(d) Any person whose interest may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR 2.309. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.309.

(e) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.159.

§ 52.179 Criteria for renewal.

The Commission may grant the renewal if the Commission determines:

(a) The manufacturing license complies with the Atomic Energy Act and the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; and

(b) Any new requirements the Commission may wish to impose are:

(1) Necessary for adequate protection to public health and safety or common defense and security;

(2) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the site permit was originally issued; or

(3) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

§ 52.181 Duration of renewal.

A renewed manufacturing license may be valid for not less than 5, nor more than 15 years from the date of renewal, and shall be subject to the requirements of §§ 52.171 and 52.175.

Subpart G [RESERVED]

Subpart H – Enforcement

§ 52.301 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 52.303 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under Sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in this part 52 are issued under one or more of Sections 161b, 161i, or 160o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in this part 52 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 52.0, 52.1, 52.2, 52.3, 52.7, 52.8, 52.9, 52.10, 52.10a, 52.11, 52.13, 52.15, 52.16, 52.17, 52.18, 52.21, 52.23, 52.24, 52.27, 52.28, 52.29, 52.31, 52.33, 52.39, 52.41, 52.43, 52.45, 52.46, 52.47, 52.48, 52.51, 52.53, 52.54, 52.55, 52.57, 52.59, 52.63, 52.71, 52.73, 52.75, 52.77, 52.79, 52.80, 52.81, 52.83, 52.85, 52.87, 52.93, 52.97, 52.98, 52.99, 52.103, 52.104, 52.105, 52.107, 52.109, 52.131, 52.133, 52.135, 52.136, 52.137, 52.139, 52.141, 52.143, 52.145, 52.147, 52.151, 52.153, 52.155, 52.156, 52.157, 52.159, 52.163, 52.165, 52.167, 52.171, 52.173, 52.175, 52.177, 52.179, 52.181, 52.301, and 52.303.

APPENDIX A TO PART 52 - DESIGN CERTIFICATION RULE FOR THE U.S. ADVANCED BOILING WATER REACTOR

I. Introduction

Appendix A constitutes the standard design certification for the U.S. Advanced Boiling Water Reactor (ABWR) design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the U.S. ABWR design was GE Nuclear Energy.

II. Definitions

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information.

Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

E. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (hereinafter Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.47, with the exception of generic technical specifications and conceptual design information;
2. Information required for a final safety analysis report under 10 CFR 50.34;
3. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
4. Combined license (COL) action items (COL license information), which identify certain matters that shall be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. Tier 2* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2* information under Section VIII.B.6.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

(1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2 or 52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Tier 1, Tier 2, and the generic technical specifications in the U.S. ABWR Design Control Document, GE Nuclear Energy, Revision 4 dated March 1997, are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 10 CFR part 51. Copies of the generic DCD may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. A copy is available for examination and copying at the NRC Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20582 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2, and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information, as set forth in the generic DCD, and the "Technical Support Document for the ABWR" are not part of this appendix. Tier 2 references to

the probabilistic risk assessment (PRA) in the ABWR standard safety analysis report do not incorporate the PRA into Tier 2.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the U.S. ABWR design or NUREG-1503, "Final Safety Evaluation Report related to the Certification of the Advanced Boiling Water Reactor Design," (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.78, and 52.79, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;

2. Include, as part of its application:

a. A plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD for the U.S. ABWR design, as modified and supplemented by the applicant's exemptions and departures;

b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;

c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;

d. Information demonstrating compliance with the site parameters and interface requirements;

- e. Information that addresses the COL action items; and
 - f. Information required by 10 CFR 52.47(a) that is not within the scope of this appendix.
3. Physically include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the U.S. ABWR DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR Part 50.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the U.S. ABWR design are in 10 CFR parts 20, 50, 73, and 100, codified as of May 2, 1997, that are applicable and technically relevant, as described in the FSER (NUREG-1503) and Supplement No. 1.

B. The U.S. ABWR design is exempt from portions of the following regulations:

- 1. Paragraph (f)(2)(iv) of 10 CFR 50.34—Separate Plant Safety Parameter Display Console;
- 2. Paragraph (f)(2)(viii) of 10 CFR 50.34—Post-Accident Sampling for Boron, Chloride, and Dissolved Gases; and
- 3. Paragraph (f)(3)(iv) of 10 CFR 50.34—Dedicated Containment Penetration.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the U.S. ABWR design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems,

components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the U.S. ABWR design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(5) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements), and the rulemaking record for certification of the U.S. ABWR design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the U.S. ABWR design;

3. All generic changes to the DCD under and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 pursuant to and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC's final environmental assessment for the U.S. ABWR design and Revision 1 of the technical support document for the U.S. ABWR, dated December

1994, for plants referencing this appendix whose site parameters are within those specified in the technical support document.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the DCD for the U.S. ABWR design, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from GE Nuclear Energy. The request must state with particularity:

- a. The nature of the proprietary or other information sought;
- b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;

c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If GE Nuclear Energy declines to provide the information sought, GE Nuclear Energy shall send a written response within 10 days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to GE Nuclear Energy), and GE Nuclear Energy's response. The Commission and presiding officer may order GE Nuclear Energy to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from June 11, 1997, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(4).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.97(b). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 50.7 are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition the NRC to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this

appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Fuel burnup limit (4.2).
- (2) Fuel design evaluation (4.2.3).
- (3) Fuel licensing acceptance criteria (appendix 4B).

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) ASME Boiler & Pressure Vessel Code, Section III.

- (2) ACI 349 and ANSI/AISC–690.
- (3) Motor-operated valves.
- (4) Equipment seismic qualification methods.
- (5) Piping design acceptance criteria.
- (6) Fuel system and assembly design (4.2), except burnup limit.
- (7) Nuclear design (4.3).
- (8) Equilibrium cycle and control rod patterns (App. 4A).
- (9) Control rod licensing acceptance criteria (App. 4C).
- (10) Instrument setpoint methodology.
- (11) EMS performance specifications and architecture.
- (12) SSLC hardware and software qualification.
- (13) Self-test system design testing features and commitments.
- (14) Human factors engineering design and implementation process.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic technical specifications and other operational requirements are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-

specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been met.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been met, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find

the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.103(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.98 and Section VIII of this appendix.

X. Records and Reporting

A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1 and Tier 2. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes and the plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes the finding required by 10 CFR 52.103(g), the report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 10 CFR 50.71(e)(4), respectively, or at shorter intervals as specified in the license.

APPENDIX B TO PART 52 - DESIGN CERTIFICATION RULE FOR THE SYSTEM 80+ DESIGN

I. Introduction

Appendix B constitutes design certification for the System 80+¹³ standard plant design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the System 80+ design was Combustion Engineering, Inc. (ABB-CE), which is now Westinghouse Electric Company LLC.

II. Definitions

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

¹³ “System 80+” is a trademark of Westinghouse Electric Company LLC.

E. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (hereinafter Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.47, with the exception of generic technical specifications and conceptual design information;
2. Information required for a final safety analysis report under 10 CFR 50.34;
3. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
4. Combined license (COL) action items (COL license information), which identify certain matters that shall be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. Tier 2* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2* information under Section VIII.B.6 of this appendix.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

(1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2 or 52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Tier 1, Tier 2, and the generic technical specifications in the System 80+ Design Control Document, ABB-CE, with revisions dated January 1997, are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the generic DCD may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. A copy is available for examination and copying at the NRC Public Document Room located at One White Flint North 11555 Rockville Pike (first floor) Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20582 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2, and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information, as set forth in the generic DCD, and the Technical Support Document for the System 80+ design are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the System 80+ design or NUREG-1462, "Final Safety Evaluation Report Related to the Certification of the System 80+ Design," (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.78, and 52.79, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;
2. Include, as part of its application:
 - a. A plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD for the System 80+ design, as modified and supplemented by the applicant's exemptions and departures;
 - b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;
 - c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;
 - d. Information demonstrating compliance with the site parameters and interface requirements;
 - e. Information that addresses the COL action items; and
 - f. Information required by 10 CFR 52.47(a) that is not within the scope of this appendix.

3. Physically include, in the plant-specific DCD, the proprietary information referenced in the System 80+ DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the System 80+ design are in 10 CFR parts 20, 50, 73, and 100, codified as of May 9, 1997, that are applicable and technically relevant, as described in the FSER (NUREG-1462) and Supplement No. 1.

B. The System 80+ design is exempt from portions of the following regulations:

1. Paragraph (f)(2)(iv) of 10 CFR 50.34—Separate Plant Safety Parameter Display Console;

2. Paragraphs (f)(2) (vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34—Accident Source Terms;

3. Paragraph (f)(2)(viii) of 10 CFR 50.34—Post-Accident Sampling for Hydrogen, Boron, Chloride, and Dissolved Gases;

4. Paragraph (f)(3)(iv) of 10 CFR 50.34—Dedicated Containment Penetration; and

5. Paragraphs III.A.1(a) and III.C.3(b) of Appendix J to 10 CFR 50—Containment Leakage Testing.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the System 80+ design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion

that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the System 80+ design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(5) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements), and the rulemaking record for certification of the System 80+ design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the System 80+ design;

3. All generic changes to the DCD under and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC's final environmental assessment for the

System 80+ design and the technical support document for the System 80+ design, dated January 1995, for plants referencing this appendix whose site parameters are within those specified in the technical support document.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary information or other secondary references in the DCD for the System 80+ design, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse. The request must state with particularity:

- a. The nature of the proprietary or other information sought;

b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;

c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within 10 days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from June 20, 1997, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(4).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.97(b). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 52.7 are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would - -

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if - -

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition the NRC to admit into the proceeding such a

contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

(1) Maximum fuel rod average burnup.

(2) Control room human factors engineering.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) ASME Boiler & Pressure Vessel Code, Section III.
- (2) ACI 349 and ANSI/AISC–690.
- (3) Motor-operated valves.
- (4) Equipment seismic qualification methods.
- (5) Piping design acceptance criteria.
- (6) Fuel and control rod design, except burnup limit.
- (7) Instrumentation and controls setpoint methodology.
- (8) Instrumentation and controls hardware and software changes.
- (9) Instrumentation and controls environmental qualification.
- (10) Seismic design criteria for non-seismic category I structures.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic technical specifications and other operational requirements are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special

circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such a petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been met.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been met, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of Section VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.103(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.98 and Section VIII of this appendix.

X. Records and Reporting

A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1 and Tier 2. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes the finding required by 10 CFR 52.103(g), the report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), the reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e)(4), respectively, or at shorter intervals as specified in the license.

APPENDIX C TO PART 52 - DESIGN CERTIFICATION RULE FOR THE AP600 DESIGN

1. Introduction

Appendix C constitutes the standard design certification for the AP600¹⁴ design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the AP600 design is Westinghouse Electric Company LLC.

II. Definitions

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information.

Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

¹⁴AP600 is a trademark of Westinghouse Electric Company LLC.

E. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (hereinafter Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.47, with the exception of generic technical specifications and conceptual design information;
2. Information required for a final safety analysis report under 10 CFR 50.34;
3. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
4. Combined license (COL) action items (combined license information), which identify certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.
5. The investment protection short-term availability controls in Section 16.3 of the DCD.

F. Tier 2* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2* information under Section VIII.B.6.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

(1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2 or 52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3), and the generic technical specifications in the AP600 DCD (12/99 revision) are approved for incorporation by reference by the Director of the Office of the Federal Register on January 24, 2000, in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the generic DCD may be obtained from Ronald P. Vijuk, Manager, Passive Plant Engineering, Westinghouse Electric Company, P.O. Box 355, Pittsburgh, Pennsylvania 15230-0355. A copy of the generic DCD is available for examination and copying at the NRC Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20582; and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3), and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information in the generic DCD and the evaluation of severe

accident mitigation design alternatives in Appendix 1B of the generic DCD are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the AP600 design or NUREG-1512, "Final Safety Evaluation Report Related to Certification of the AP600 Standard Design," (FSER), then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.78, and 52.79, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;
2. Include, as part of its application:
 - a. A plant-specific DCD containing the same type of information and utilizing the same organization and numbering as the generic DCD for the AP600 design, as modified and supplemented by the applicant's exemptions and departures;
 - b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;
 - c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;
 - d. Information demonstrating compliance with the site parameters and interface requirements;
 - e. Information that addresses the COL action items; and

- f. Information required by 10 CFR 52.47(a) that is not within the scope of this appendix.
3. Physically include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the AP600 DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the AP600 design are in 10 CFR parts 20, 50, 73, and 100, codified as of December 16, 1999, that are applicable and technically relevant, as described in the FSER (NUREG-1512) and the supplementary information for this section.

B. The AP600 design is exempt from portions of the following regulations:

1. Paragraph (a)(1) of 10 CFR 50.34—whole body dose criterion;
2. Paragraph (f)(2)(iv) of 10 CFR 50.34—Plant Safety Parameter Display Console;
3. Paragraphs (f)(2)(vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34—Accident Source Term in TID 14844;
4. Paragraph (a)(2) of 10 CFR 50.55a—ASME Boiler and Pressure Vessel Code;
5. Paragraph (c)(1) of 10 CFR 50.62—Auxiliary (or emergency) feedwater system;
6. Appendix A to 10 CFR Part 50, GDC 17—Offsite Power Sources; and
7. Appendix A to 10 CFR Part 50, GDC 19—whole body dose criterion.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the AP600 design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that

a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the AP600 design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(5) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements and the investment protection short-term availability controls in Section 16.3), and the rulemaking record for certification of the AP600 design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the AP600 design;

3. All generic changes to the DCD under and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives (SAMDA) associated with the information in the NRC's environmental assessment for the AP600 design and appendix 1B of the generic DCD, for plants referencing this appendix whose site parameters are within those specified in the SAMDA evaluation.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the AP600 DCD, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse. The request must state with particularity:

- a. The nature of the proprietary or other information sought;

b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;

c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.85 or 10 CFR 52.103. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within 10 days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from January 24, 2000, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(4).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and § 52.97(b). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 52.7 are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment under paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition the NRC to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this

appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Maximum fuel rod average burn-up.
- (2) Fuel principal design requirements.
- (3) Fuel criteria evaluation process.
- (4) Fire areas.
- (5) Human factors engineering.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves

full power, the following Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) Nuclear Island structural dimensions.
- (2) ASME Boiler and Pressure Vessel Code, Section III, and Code Case –284.
- (3) Design Summary of Critical Sections.
- (4) ACI 318, ACI 349, and ANSI/AISC—690.
- (5) Definition of critical locations and thicknesses.
- (6) Seismic qualification methods and standards.
- (7) Nuclear design of fuel and reactivity control system, except burn-up limit.
- (8) Motor-operated and power-operated valves.
- (9) Instrumentation and control system design processes, methods, and standards.
- (10) PRHR natural circulation test (first plant only).
- (11) ADS and CMT verification tests (first three plants only).

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic technical specifications and other operational requirements are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-

specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been met.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been met, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find

the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.103(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.98 and Section VIII of this appendix.

X. Records and Reporting

A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1 and Tier 2. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates must be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 52.3 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes the finding required by 10 CFR 52.103(g), the report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by 10 CFR 52.103(g), the reports and updates to the plant-specific DCD must be submitted annually or along with updates to the site-specific portion of the final safety analysis report for the facility at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e), respectively, or at shorter intervals as specified in the license.

**PART 54 - REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR
POWER PLANTS**

130. The authority citation for Part 54 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 161, 181, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs 201, 202, 206, 88 Stat. 1242, 1244, as amended (42 U.S.C. 5841, 5842).

Section 54.17 also issued under E.O.12829, 3 CFR, 1993 Comp., p. 570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p. 333; E.O. 12968, 3 CFR, 1995 Comp., p. 391.

131. Section 54.1 is revised to read as follows:

§ 54.1 Purpose.

This part governs the issuance of renewed operating licenses and renewed combined licenses for nuclear power plants licensed pursuant to Sections 103 or 104b of the Atomic Energy Act of 1954, as amended, and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242).

132. In § 54.3, paragraph (a), the definition for *Current licensing basis* is revised, and the definition for *Renewed combined license* is added to read as follows:

§ 54.3 Definitions.

(a) * * *

Current licensing basis (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect.

The CLB includes the NRC regulations contained in 10 CFR parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

* * * * *

Renewed combined license means a combined license originally issued under part 52 of this chapter for which an application for renewal is filed in accordance with 10 CFR 52.107 and issued under this part.

* * * * *

133. In § 54.17, paragraph (c) is revised to read as follows:

§ 54.17 Filing of application.

* * * * *

(c) An application for a renewed license may not be submitted to the Commission earlier than 20 years before the expiration of the operating license or combined license currently in effect.

* * * * *

134. Section 54.27 is revised to read as follows:

§ 54.27 Hearings.

A notice of an opportunity for a hearing will be published in the *Federal Register* in accordance with 10 CFR 2.105. In the absence of a request for a hearing filed within 30 days by a person whose interest may be affected, the Commission may issue a renewed operating license or renewed combined license without a hearing upon 30-day notice and publication in the *Federal Register* of its intent to do so.

135. In Section 54.31, paragraphs (a), (b), and (c) are revised to read as follows:

§ 54.31 Issuance of a renewed license.

(a) A renewed license will be of the class for which the operating license or combined license currently in effect was issued.

(b) A renewed license will be issued for a fixed period of time, which is the sum of the additional amount of time beyond the expiration of the operating license or combined license (not to exceed 20 years) that is requested in a renewal application plus the remaining number of years on the operating license or combined license currently in effect. The term of any renewed license may not exceed 40 years.

(c) A renewed license will become effective immediately upon its issuance, thereby superseding the operating license or combined license previously in effect. If a renewed license is subsequently set aside upon further administrative or judicial appeal, the operating license or combined license previously in effect will be reinstated unless its term has expired and the renewal application was not filed in a timely manner.

* * * * *

136. Section 54.35 is revised to read as follows:

§ 54.35 Requirements during term of renewed license.

During the term of a renewed license, licensees shall be subject to and shall continue to comply with all Commission regulations contained in 10 CFR parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, and 100, and the appendices to these parts that are applicable to holders of operating licenses or combined licenses, respectively.

137. In § 54.37, paragraph (a) is revised to read as follows:

§ 54.37 Additional records and recordkeeping requirements.

(a) The licensee shall retain in an auditable and retrievable form for the term of the renewed operating license or renewed combined license all information and documentation required by, or otherwise necessary to document compliance with, the provisions of this part.

* * * * *

PART 55 - OPERATORS' LICENSES

138. The authority citation for Part 55 continues to read as follows:

AUTHORITY: Secs. 107, 161, 182, 68 Stat. 939, 948, 953 , as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2137, 2201, 2232, 2282); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Sections 55.41, 55.43, 55.45, and 55.59 also issued under sec. 306, Pub. L. 97-425, 96 Stat. 2262 (42 U.S.C. 10226). Section 55.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237).

139. In § 55.1, paragraph (a) is revised to read as follows:

§ 55.1 Purpose.

* * * * *

(a) Establish procedures and criteria for the issuance of licenses to operators and senior operators of utilization facilities licensed under the Atomic Energy Act of 1954, as amended, or Section 202 of the Energy Reorganization Act of 1974, as amended, and part 50, part 52, or part 54 of this chapter,

* * * * *

140. In § 55.2, paragraph (a) is revised to read as follows:

§ 55.2 Scope.

* * * * *

(a) Any individual who manipulates the controls of any utilization facility licensed under parts 50, 52, or 54 of this chapter,

* * * * *

141. In § 55.5, paragraph (b)(1) and the inductive text of paragraph (b)(2) are revised to read as follows:

§ 55.5 Communications.

* * * * *

(b)(1) Except for test and research reactor facilities, the Director of Nuclear Reactor Regulation has delegated to the Regional Administrators of Regions I, II, III, and IV authority and responsibility under the regulations in this part for the issuance and renewal of licenses for operators and senior operators of nuclear power reactors licensed under 10 CFR part 50 or part 52 and located in these regions.

(2) Any application for a license or license renewal filed under the regulations in this part involving a nuclear power reactor licensed under 10 CFR part 50 or part 52 and any related inquiry, communication, information, or report must be submitted to the Regional Administrator

by an appropriate method listed in paragraph (a) of this section. The Regional Administrator or the Administrator's designee will transmit to the Director of Nuclear Reactor Regulation any matter that is not within the scope of the Regional Administrator's delegated authority.

* * * * *

**PART 72 - LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT
NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE AND REACTOR RELATED
GREATER THAN CLASS C WASTE**

142. The authority citation for Part 72 continues to read as follows:

AUTHORITY: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101,

10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

143. Section 72.210 is revised to read as follows:

§ 72.210 General license issued.

A general license is hereby issued for the storage of spent fuel in an independent spent fuel storage installation at power reactor sites to persons authorized to possess or operate nuclear power reactors under 10 CFR part 50 or 10 CFR part 52.

144. In § 72.218, paragraph (b) is revised to read as follows:

§ 72.218 Termination of licenses.

* * * * *

(b) An application for termination of a reactor operating license issued under 10 CFR part 50 and submitted under § 50.82 of this chapter, or a combined license issued under 10 CFR part 52 and submitted under § 52.110 of this chapter, must contain a description of how the spent fuel stored under this general license will be removed from the reactor site.

* * * * *

PART 73 - PHYSICAL PROTECTION OF PLANTS AND MATERIALS

145. The authority citation for Part 73 continues to read as follows:

AUTHORITY: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C, 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99-399, 100 Stat. 876 (42 U.S.C. 2169).

146. In § 73.1, paragraph (b)(1)(i) is revised to read as follows:

§ 73.1 Purpose and scope.

* * * * *

(b) * * *

(1) * * *

(i) The physical protection of production and utilization facilities licensed under parts 50 or 52 of this chapter,

* * * * *

147. In § 73.2, the introductory text of paragraph (a) is revised to read as follows:

§ 73.2 Definitions.

* * * * *

(a) Terms defined in parts 50, 52, and 70 of this chapter have the same meaning when used in this part.

* * * * *

148. In § 73.50, the introductory text is revised to read as follows:

§ 73.50 Requirements for physical protection of licensed activities.

Each licensee who is not subject to § 73.51, but who possesses, uses, or stores formula quantities of strategic special nuclear material that are not readily separable from other

radioactive material and which have total external radiation dose rates in excess of 100 rems per hour at a distance of 3 feet from any accessible surfaces without intervening shielding other than at nuclear reactor facility licensed under parts 50 or 52 of this chapter, shall comply with the following:

* * * * *

149. In § 73.56, paragraph (a)(3) is revised to read as follows:

§ 73.56 Personnel access authorization requirements for nuclear power plants.

(a) * * *

(3) Each applicant for a license to operate a nuclear power reactor under §§ 50.21(b) or 50.22 of this chapter, including an applicant for a combined license under part 52 of this chapter, whose application is submitted after April 25, 1991, shall include the required access authorization program as part of its Physical Security Plan. The applicant, upon receipt of an operating license or upon notice of the Commission's finding under § 52.103(g) of this chapter, shall implement the required access authorization program as part of its site Physical Security Plan.

* * * * *

150. In § 73.57, paragraphs (a)(1), (a)(2), and (a)(3) are revised to read as follows:

§ 73.57 Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information by power reactor licensees.

(a) * * *

(1) Each licensee who is authorized to operate a nuclear power reactor under part 50 of this chapter, or each holder of a combined license under part 52 of this chapter upon receipt of

notice of the Commission's finding under § 52.103(g), shall comply with the requirements of this section.

(2) Each applicant for a license to operate a nuclear power reactor under part 50 of this chapter and each applicant for a combined license under part 52 of this chapter shall submit fingerprints for those individuals who have or will have access to Safeguards Information.

(3) Before receiving its operating license under part 50 of this chapter or before the Commission makes its finding under § 52.103(g) of this chapter, each applicant for a license to operate a nuclear power reactor (including an applicant for a combined license) may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility.

* * * * *

151. In Appendix C to Part 73, the Introduction is revised to read as follows:

APPENDIX C TO PART 73--LICENSEE SAFEGUARDS CONTINGENCY PLANS

Introduction

A licensee safeguards contingency plan is a documented plan to give guidance to licensee personnel in order to accomplish specific defined objectives in the event of threats, thefts, or radiological sabotage relating to special nuclear material or nuclear facilities licensed under the Atomic Energy Act of 1954, as amended. An acceptable safeguards contingency plan must contain: (1) a predetermined set of decisions and actions to satisfy stated objectives, (2) an identification of the data, criteria, procedures, and mechanisms necessary to efficiently implement the decisions, and (3) a stipulation of the individual, group, or organizational entity responsible for each decision and action.

The goals of licensee safeguards contingency plans for responding to threats, thefts, and radiological sabotage are:

- (1) to organize the response effort at the licensee level,
- (2) to provide predetermined, structured responses by licensees to safeguards contingencies,
- (3) to ensure the integration of the licensee response with the responses by other entities, and
- (4) to achieve a measurable performance in response capability.

Licensee safeguards contingency planning should result in organizing the licensee's resources in such a way that the participants will be identified, their several responsibilities specified, and the responses coordinated. The responses should be timely.

It is important to note that a licensee's safeguards contingency plan is intended to be complementary to any emergency plans developed under appendix E to part 50 of this chapter, § 52.17 or § 52.79, or to § 70.22(i) of this chapter.

* * * * *

PART 75 - SAFEGUARDS ON NUCLEAR MATERIAL - IMPLEMENTATION OF US/IAEA AGREEMENT

152. The authority citation for Part 75 continues to read as follows

AUTHORITY: Secs. 53, 63, 103, 104, 122, 161, 68 Stat. 930, 932, 936, 937, 939, 948, as amended (42 U.S.C. 2073, 2093, 2133, 2134, 2152, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 75.4 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

153. In § 75.6, paragraph (b) is revised to read as follows:

§ 75.6 Maintenance of records and delivery of information, reports, and other communications.

* * * * *

(b) If an installation is a nuclear power plant or a non-power reactor for which a construction permit, operating license or a combined license has been issued, whether or not a license to receive and possess nuclear material at the installation has been issued, the cognizant Director is the Director, Office of Nuclear Reactor Regulation. For all other installations, the cognizant Director is the Director, Office of Nuclear Material Safety and Safeguards.

* * * * *

PART 95 - FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

154. The authority citation for Part 95 continues to read as follows:

AUTHORITY: Secs. 145, 161, 193, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); E.O. 10865, as amended, 3 CFR 1959-1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12829, 3 CFR, 1993 Comp., p. 570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p. 333, as amended by E.O. 13292, 3 CFR, 2004 Comp., p. 196; E.O. 12968, 3 CFR, 1995 Comp., p. 391.

155. In § 95.5, the definition of *license* is revised to read as follows:

§ 95.5 Definitions.

* * * * *

License means a license issued under 10 CFR parts 50, 52, 54, 60, 63, 70, or 72.

* * * * *

156. In § 95.13, paragraph (b) is revised to read as follows:

§ 95.13 Maintenance of records.

* * * * *

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee, certificate holder, or other person shall maintain adequate safeguards against tampering with and loss of records.

157. In § 95.19, the introductory text of paragraph (b) is revised to read as follows:

§ 95.19 Changes to security practices and procedures.

* * * * *

(b) A licensee, certificate holder, or other person may effect a minor, non-substantive change to an approved Standard Practice Procedures Plan for the safeguarding of classified information without receiving prior CSA approval. These minor changes that do not affect the security of the facility may be submitted to the addressees noted in paragraph (a) of this section within 30 days of the change. Page changes rather than a complete rewrite of the plan may be submitted. Some examples of minor, non-substantive changes to the Standard Practice Procedures Plan include—

* * * * *

158. Section 95.20 is revised to read as follows:

§ 95.20 Grant, denial or termination of facility clearance.

The Division of Nuclear Security shall provide notification in writing (or orally with written confirmation) to the licensee, certificate holder, or other person of the Commission's grant, acceptance of another agency's facility clearance, denial, or termination of facility clearance. This information must also be furnished to representatives of the NRC, NRC contractors, licensees, certificate holders, or other person, or other Federal agencies having a need to transmit classified information to the licensees or other person.

159. In § 95.23, paragraph (b) is revised to read as follows:

§ 95.23 Termination of facility clearance.

* * * * *

(b) When facility clearance is terminated, the licensee, certificate holder, or other person will be notified in writing of the determination and the procedures outlined in § 95.53 apply.

160. Section 95.31 is revised to read as follows:

§ 95.31 Protective personnel.

Whenever protective personnel are used to protect classified information they shall:

(a) Possess an "L" access authorization (or CSA equivalent) if the licensee, certificate holder, or other person possesses information classified Confidential National Security Information, Confidential Restricted Data or Secret National Security Information.

(b) Possess a "Q" access authorization (or CSA equivalent) if the licensee, certificate holder, or other person possesses Secret Restricted Data related to nuclear weapons design,

manufacturing and vulnerability information; and certain particularly sensitive Naval Nuclear Propulsion Program information (e.g., fuel manufacturing technology) and the protective personnel require access as part of their regular duties.

161. In § 95.33, paragraph (c) is revised to read as follows:

§ 95.33 Security education.

* * * * *

(c) Temporary Help Suppliers. A temporary help supplier, or other contractor who employs cleared individuals solely for dispatch elsewhere, is responsible for ensuring that required briefings are provided to their cleared personnel. The temporary help supplier or the using licensee's, certificate holder's, or other person's facility may conduct these briefings.

* * * * *

162. Section 95.34 is revised to read as follows:

§ 95.34 Control of visitors.

(a) Uncleared visitors. Licensees, certificate holders, or other persons subject to this part shall take measures to preclude access to classified information by uncleared visitors.

(b) Foreign visitors. Licensees, certificate holders, or other persons subject to this part shall take measures as may be necessary to preclude access to classified information by foreign visitors. The licensee, certificate holder, or other person shall retain records of visits for 5 years beyond the date of the visit.

163. In § 95.35, the introductory text of paragraph (a), and paragraph (a)(3) are revised to read as follows:

§ 95.35 Access to matters classified as National Security Information and Restricted Data.

(a) Except as the Commission may authorize, no licensee, certificate holder or other person subject to the regulations in this part may receive or may permit any other licensee, certificate holder, or other person to have access to matter revealing Secret or Confidential National Security Information or Restricted Data unless the individual has:

* * * * *

(3) NRC-approved storage facilities if classified documents or material are to be transmitted to the licensee, certificate holder, or other person.

* * * * *

164. In § 95.36, paragraphs (c), (d) and (e) are revised to read as follows:

§ 95.36 Access by representatives of the International Atomic Energy Agency or by participants in other international agreements.

* * * * *

(c) In accordance with the specific disclosure authorization provided by the Division of Nuclear Security, licensees, certificate holders, or other persons subject to this part are authorized to release (i.e., transfer possession of) copies of documents that contain classified National Security Information directly to IAEA inspectors and other representatives officially designated to request and receive classified National Security Information documents. These documents must be marked specifically for release to IAEA or other international organizations in accordance with instructions contained in the NRC's disclosure authorization letter. Licensees, certificate holders, and other persons subject to this part may also forward these documents through the NRC to the international organization's headquarters in accordance with the NRC disclosure authorization. Licensees, certificate holders, and other persons may not

reproduce documents containing classified National Security Information except as provided in § 95.43.

(d) Records regarding these visits and inspections must be maintained for 5 years beyond the date of the visit or inspection. These records must specifically identify each document released to an authorized representative and indicate the date of the release. These records must also identify (in such detail as the Division of Nuclear Security, by letter, may require) the categories of documents that the authorized representative has had access and the date of this access. A licensee, certificate holder, or other person subject to this part shall also retain Division of Nuclear Security disclosure authorizations for 5 years beyond the date of any visit or inspection when access to classified information was permitted.

(e) Licensees, certificate holders, or other persons subject to this part shall take such measures as may be necessary to preclude access to classified matter by participants of other international agreements unless specifically provided for under the terms of a specific agreement.

165. In § 95.37, paragraphs (a), (b) and (h) are revised to read as follows:

§ 95.37 Classification and preparation of documents.

(a) *Classification.* Classified information generated or possessed by a licensee, certificate holder, or other person must be appropriately marked. Classified material which is not conducive to markings (e.g., equipment) may be exempt from this requirement. These exemptions are subject to the approval of the CSA on a case-by-case basis. If a person or facility generates or possesses information that is believed to be classified based on guidance provided by the NRC or by derivation from classified documents, but which no authorized classifier has determined to be classified, the information must be protected and marked with the appropriate classification markings pending review and signature of an NRC authorized

classifier. This information shall be protected as classified information pending final determination.

(b) *Classification consistent with content.* Each document containing classified information shall be classified Secret or Confidential according to its content. NRC licensees, certificate holders, or other persons subject to the requirements of 10 CFR part 95 may not make original classification decisions.

* * * * *

(h) *Classification challenges.* Licensees, certificate holders, or other persons in authorized possession of classified National Security Information who in good faith believe that the information's classification status (i.e., that the document), is classified at either too high a level for its content (overclassification) or too low for its content (underclassification) are expected to challenge its classification status. Licensees, certificate holders, or other persons who wish to challenge a classification status shall—

(1) Refer the document or information to the originator or to an authorized NRC classifier for review. The authorized classifier shall review the document and render a written classification decision to the holder of the information.

(2) In the event of a question regarding classification review, the holder of the information or the authorized classifier shall consult the NRC Division of Facilities and Security, Information Security Branch, for assistance.

(3) Licensees, certificate holders, or other persons who challenge classification decisions have the right to appeal the classification decision to the Interagency Security Classification Appeals Panel.

(4) Licensees, certificate holders, or other persons seeking to challenge the classification of information will not be the subject of retribution.

* * * * *

166. In § 95.39, paragraph (a) is revised to read as follows:

§ 95.39 External transmission of documents and material.

(a) Restrictions. Documents and material containing classified information received or originated in connection with an NRC license, certificate, or standard design approval or standard design certification under part 52 of this chapter must be transmitted only to CSA approved security facilities.

* * * * *

167. In § 95.43, paragraph (a) is revised to read as follows:

§ 95.43 Authority to reproduce.

(a) Each licensee, certificate holder, or other person possessing classified information shall establish a reproduction control system to ensure that reproduction of classified material is held to the minimum consistent with operational requirements. Classified reproduction must be accomplished by authorized employees knowledgeable of the procedures for classified reproduction. The use of technology that prevents, discourages, or detects the unauthorized reproduction of classified documents is encouraged.

* * * * *

168. In § 95.45, paragraph (d) is revised to read as follows:

§ 95.45 Changes in classification.

* * * * *

(d) Any licensee, certificate holder, or other person making a change in classification or receiving notice of such a change shall forward notice of the change in classification to holders of all copies as shown on their records.

169. Section 95.49 is revised to read as follows:

§ 95.49 Security of automatic data processing (ADP) systems.

Classified data or information may not be processed or produced on an ADP system unless the system and procedures to protect the classified data or information have been approved by the CSA. Approval of the ADP system and procedures is based on a satisfactory ADP security proposal submitted as part of the licensee's, certificate holder's, or other person's request for facility clearance outlined in § 95.15 or submitted as an amendment to its existing Standard Practice Procedures Plan for the protection of classified information.

170. Section 95.51 is revised to read as follows:

§ 95.51 Retrieval of classified matter following suspension or revocation of access authorization.

In any case where the access authorization of an individual is suspended or revoked in accordance with the procedures set forth in part 25 of this chapter, or other relevant CSA procedures, the licensee, certificate holder, or other person shall, upon due notice from the Commission of such suspension or revocation, retrieve all classified information possessed by the individual and take the action necessary to preclude that individual having further access to the information.

171. Section 95.53 is revised to read as follows:

§ 95.53 Termination of facility clearance.

(a) If the need to use, process, store, reproduce, transmit, transport, or handle classified matter no longer exists, the facility clearance will be terminated. The licensee, certificate holder, or other person for the facility may deliver all documents and matter containing classified information to the Commission, or to a person authorized to receive them, or must destroy all

classified documents and matter. In either case, the licensee, certificate holder, or other person for the facility shall submit a certification of nonpossession of classified information to the NRC Division of Nuclear Security within 30 days of the termination of the facility clearance.

(b) In any instance where a facility clearance has been terminated based on a determination of the CSA that further possession of classified matter by the facility would not be in the interest of the national security, the licensee, certificate holder, or other person for the facility shall, upon notice from the CSA, dispose of classified documents in a manner specified by the CSA.

172. In § 95.57, the introductory paragraph is revised to read as follows:

§ 95.57 Reports.

Each licensee, certificate holder, or other person having a facility clearance shall report to the CSA and the Regional Administrator of the appropriate NRC Regional Office listed in 10 CFR part 73, appendix A:

* * * * *

173. Section 95.59 is revised to read as follows:

§ 95.59 Inspections.

The Commission shall make inspections and reviews of the premises, activities, records and procedures of any licensee, certificate holder, or other person subject to the regulations in this part as the Commission and CSA deem necessary to effect the purposes of the Act, E.O. 12958 and/or NRC rules.

PART 140 - FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY AGREEMENTS

174. The authority citation for Part 140 continues to read as follows:

AUTHORITY: Secs. 161, 170, 68 Stat. 948, 71 Stat. 576, as amended (42 U.S.C. 2201, 2210); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 841, 5842); Sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

175. In § 140.2, paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 140.2 Scope.

(a)* * *

(1) To each person who is an applicant for or holder of a license issued under 10 CFR parts 50, 52 or 54 to operate a nuclear reactor, and

(2) With respect to an extraordinary nuclear occurrence, to each person who is an applicant for or holder of a license to operate a production facility or a utilization facility (including an operating license issued under part 50 of this chapter and a combined license under part 52 of this chapter), and to other persons indemnified with respect to the involved facilities.

* * * * *

176. Section 140.10 is revised to read as follows:

§ 140.10 Scope.

This subpart applies to each person who is an applicant for or holder of a license issued under 10 CFR parts 50 or 54 to operate a nuclear reactor, or is the applicant for or holder of a combined license issued under parts 52 or 54 of this chapter, except licenses held by persons found by the Commission to be Federal agencies or nonprofit educational institutions licensed to conduct educational activities. This subpart also applies to persons licensed to possess and use plutonium in a plutonium processing and fuel fabrication plant.

177. In § 140.11, paragraph (b) is revised to read as follows:

§ 140.11 Amounts of financial protection for certain reactors.

* * * * *

(b) In any case where a person is authorized under parts 50, 52 or 54 of this chapter to operate two or more nuclear reactors at the same location, the total primary financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such primary financial protection covers all reactors at the location.

178. In § 140.12, paragraph (c) is revised to read as follows:

§ 140.12 Amount of financial protection required for other reactors.

* * * * *

(c) In any case where a person is authorized under parts 50, 52 or 54 of this chapter to operate two or more nuclear reactors at the same location, the total financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such financial protection covers all reactors at the location.

* * * * *

179. In Section 140.13, the heading and the text are revised to read as follows:

§ 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under 10 CFR part 52.

Each holder of a part 50 construction permit, or a holder of a combined license under part 52 of this chapter before the date that the Commission had made the finding under 10 CFR 52.103(g), who also holds a license under part 70 of this chapter authorizing ownership,

possession and storage only of special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of either an operating license under 10 CFR part 50 or combined license under 10 CFR part 52, shall, during the period before issuance of a license authorizing operation under parts 50, or the period before the Commission makes the finding under § 52.103(g) of this chapter, as applicable, have and maintain financial protection in the amount of \$1,000,000. Proof of financial protection shall be filed with the Commission in the manner specified in § 140.15 of this chapter before issuance of the license under part 70 of this chapter.

180. In § 140.20, paragraph (a)(1)(ii) is revised, and paragraph (a)(1)(iii) is added to read as follows:

§ 140.20 Indemnity agreements and liens.

(a)* * *

(1)* * *

(ii) The date that the Commission makes the finding under § 52.103(g) of this chapter;

or

(iii) the effective date of the license (issued under part 70 of this chapter) authorizing the licensee to possess and store special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of an operating license for the reactor, whichever is earlier. No such agreement, however, shall be effective prior to September 26, 1957; or

* * * * *

181. In § 140.81, paragraph (a) is revised to read as follows:

§ 140.81 Scope and purpose.

(a) *Scope.* This subpart applies to applicants for and holders of licenses authorizing operation of production facilities and utilization facilities, including combined licenses under part 52 of this chapter, and to other persons indemnified with respect to such facilities.

* * * * *

182. In § 140.93 Appendix C, Article VIII, paragraph 4 is revised to read as follows:

§ 140.93 Appendix C - Form of indemnity agreement with licensees furnishing proof of financial protection in the form of licensee's resources.

* * * * *

ARTICLE VIII

* * * * *

4. If the Commission determines that the licensee is financially able to reimburse the Commission for a deferred premium payment made in its behalf, and the licensee, after notice of such determination by the Commission fails to make such reimbursement within 120 days, the Commission will take appropriate steps to suspend the license for 30 days. The Commission may take any further action as necessary if reimbursement is not made within the 30-day suspension period including, but not limited to, termination of the operating license or combined license.

* * * * *

183. Section 140.96 is revised to read as follows:

§ 140.96 Appendix F – Indemnity locations.

(a) *Geographical boundaries of indemnity locations.*

(1) In every indemnity agreement between the Commission and a licensee which affords indemnity protection for the preoperational storage of fuel at the site of a nuclear power

reactor under construction, the geographical boundaries of the indemnity location will include the entire construction area of the nuclear power reactor, as determined by the Commission. Such area will not necessarily be coextensive with the indemnity location which will be established at the time an operating license or combined license under 10 CFR part 52 is issued for such additional nuclear power reactors.

(2) In every indemnity agreement between the Commission and a licensee which affords indemnity protection for an existing nuclear power reactor, the geographical boundaries of the indemnity location shall include the entire construction area of any additional nuclear power reactor as determined by the Commission, built as part of the same power station by the same licensee. Such area will not necessarily be coextensive with the indemnity location which will be established at the time an operating license or combined license is issued for such additional nuclear power reactors.

(3) This section is effective May 1, 1973, as to construction permits issued before March 2, 1973, and, as to construction permits and combined licenses issued on or after March 2, 1973, the provisions of this section will apply no later than such time as a construction permit or combined license is issued authorizing construction of any additional nuclear power reactor.

**PART 170 - FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES,
AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954,
AS AMENDED**

184. The authority citation for Part 170 continues to read as follows:

AUTHORITY: Sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, pub. L. 101-576, 104 Stat. 2842, as amended (31 U.S.C. 901, 902); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

185. In § 170.2, paragraph (j) is removed and reserved, and paragraph (g) and the introductory text of paragraph (k) are revised to read as follows:

§ 170.2 Scope.

* * * * *

(g) An applicant for or holder of a production or utilization facility construction permit or operating license issued under 10 CFR part 50, or an early site permit, standard design certification, standard design approval, manufacturing license, or combined license issued under 10 CFR part 52;

* * * * *

(j) **[Reserved]**

(k) Applying for or already has applied for review, under , appendix Q to 10 CFR part 50 of a facility site before the submission of an application for a construction permit;

* * * * *

Dated at Rockville, Maryland, this day of , 2005.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

REGULATORY ANALYSIS FOR REVISED PROPOSED RULE:
UPDATE 10 CFR 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR
NUCLEAR POWER PLANTS"

Introduction

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations by revising the provisions applicable to the licensing and approval processes for nuclear power plants and making necessary conforming amendments throughout the NRC's regulations to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. The proposed changes would clarify the applicability of various requirements to each of the licensing processes (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license).

This rulemaking to enhance 10 CFR Part 52 is based on lessons learned during design certification and early site permit (ESP) reviews, and on discussions with stakeholders about the ESP, design certification, and combined license (COL) review processes. The NRC believes that this rulemaking action will improve the effectiveness and efficiency of the licensing and approval processes for future applicants.

This regulatory analysis has been prepared in accordance with the Nuclear Regulatory Commission (NRC) Regulatory Analysis Guidelines (RA Guidelines), NUREG/BR-0058, Revision 4, dated September 2004. The regulatory analysis consists of two parts. The first is an aggregate analysis of the proposed rule. The second part is a screening review for disaggregation to identify any individual provisions whose costs are disproportionate to the potential benefits.

A. Aggregate Analysis- Summary of Results

Consistent with the RA Guidelines, the NRC performed an aggregate analysis of the proposed rule. The analysis is based on a projected business scenario reflecting the NRC's expectations of eight combined license applications (COL) during the next three years and thereafter two COL applications per year would occur over the next 17 years. The provisions of the proposed rule relating to Part 52 are estimated to result in net present value savings to the industry of \$26,015 K, and \$26,392 K using a 3-percent and a 7-percent discount rate, respectively. The provisions of the proposed rule relating to Part 21 are estimated to result in net present value cost of \$7,550 K and \$5,123 K to the industry, using a 3-percent a 7-percent discount rate, respectively. The net present value of the entire proposed rule is estimated to result in a net savings to the industry of \$18,465 K and \$21,269 K at a 3- percent and a 7-percent discount rate, respectively. In addition, the proposed rule is estimated to be a net present value savings to the NRC of \$8,424 K and \$8,424 K at a 3- percent and a 7- percent discount rate, respectively.

The NRC concludes that the costs of the rule are justified in view of the quantitative savings and evaluation and discussion of qualitative benefits in Section 5.1. The analysis measures the incremental value of the proposed rule vis-a-vis the current rule. A summary of the analysis is presented in Section 5.2.

B. Screening Review for Disaggregation

The NRC also performed a screening review for disaggregation in accordance with Section

4.3.2 of the RA Guidelines to determine if there are provisions whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could mask the true impact. This analysis also responds to the Commission's direction in SRM-01-0134, dated July 23, 2001: "If there is a reasonable indication that a proposed change imposes costs disproportionate to the safety benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed changes for the purposes of backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR 50.109(a)(4)." The results of the analysis are documented in Section 5.2.

1. Statement of Problem and Objective

The NRC published 10 CFR Part 52, “Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants” in April 1989. The NRC now proposes to revise these requirements through a reorganization, clarification and rewrite of Part 52. The staff is also proposing clarification and corrections to 10 CFR Parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52 (including appendices A, B, and C), 54, 55, 72, 73, 75, 95, 140, and 170. The proposed rule reflects lessons learned from the Commission’s experience in design certification and early site permit reviews, input from stakeholders, as appropriate, on the combined license process, and corrects known errors and omissions. This action is expected to improve the effectiveness and efficiency of Part 52 licensing processes for future applicants. The major objectives of this rulemaking are to —

- increase regulatory efficiency
- reduce unnecessary regulatory burden
- address issues and incorporate lessons learned from the Part 52 licensing processes
- make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes
- address omissions and errors identified since the promulgation of Part 52
- clarify ambiguities in Part 52 to reflect the original intent of the NRC

This proposed action would be applicable to future applicants for early site permits, design approvals, design certifications, combined license, and manufacturing license applications. It would not affect any current licensee under Part 52 since no license has yet been issued under Part 52. However, the proposed action would affect holders of existing design certifications.

2. Background

A. Original Promulgation of Part 52

The NRC promulgated 10 CFR Part 52 on April 18, 1989 (54 FR 15386), to reform the NRC's licensing process for future nuclear power plants. The rule added alternative licensing processes in 10 CFR Part 52 for early site permits, standard design certifications, and combined licenses. The processes in 10 CFR Part 52 resolve safety and environmental issues early in licensing proceedings and enhance the safety and reliability of nuclear power plants through standardization. The rule also moved the licensing processes in Appendices M, N, O, and Q of 10 CFR Part 50 to 10 CFR Part 52. Subsequently, the NRC certified three nuclear plant designs under Subpart B of 10 CFR Part 52— the U.S. Advanced Boiling Water Reactor (ABWR) Design (62 FR 25827, May 12, 1997), the System 80+ design (62 FR 27867, May 21, 1997), and the AP600 design (64 FR 72015, December 23, 1999) and codified these designs in Appendices A, B, and C of 10 CFR Part 52, respectively.

The regulations in Part 52 provide for the certification of standardized reactor designs, making it possible to use the same design information for the licensing of several plants, and provide for the issuance of a single license for both construction and operation, eliminating the need for two applications and two submittals of design information. Part 52 also provides for the approval of a nuclear power plant site in advance of the submission of any application for a construction permit for that site. The use of standardized designs allows a more focused review and the industry can transfer experience in maintenance and operation from one plant to another more easily. In summary, the principal objective of Part 52 was to increase the effectiveness and efficiency of the licensing process for nuclear power plants by early resolution of issues.

B. July 2003 Proposed Rulemaking

The NRC planned to revise 10 CFR Part 52 after the first standard design certification reviews. In SECY-98-282, "Part 52 Rulemaking Plan", dated December 4, 1998, the staff proposed to initiate a rulemaking to revise Part 52. The NRC issued a staff requirements memorandum on January 14, 1999, approving the NRC staff's plan for revising 10 CFR Part 52. After the issuance of SECY-00-0092, Combined License Review Process, dated April 20, 2000, stakeholders at public meetings raised other licensing issues with 10 CFR Part 52 Subparts A and C (early site permits and combined licenses, respectively). The NRC obtained considerable stakeholder comments on its planned action through three public meetings on the proposed rulemaking, and two postings of draft rule language on the NRC's rulemaking Website. On July 3, 2003, (68 FR 40026) the NRC published a proposed rule that would clarify and/or correct 10 CFR Parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52 (including appendices A, B, and C), 54, 55, 72, 73, 140, 170, 171, and revise portions of 10 CFR Part 52, and incorporate stakeholders comments.

3.0 Revised Proposed Rulemaking

Following the close of the public comment period on the July 2003 proposed rule, the NRC re-evaluated whether the proposed rule would meet the Commission's objective of improving the effectiveness of NRC's processes for licensing future nuclear power plants. First, public comments identified several concerns about whether the July 2003 proposed rule adequately addressed the relationship between Part 50 and Part 52 and clearly specified the applicable regulatory requirements for each of the licensing and approval processes in Part 52. In addition, during the public comment period and thereafter, the NRC gained additional insights about early site permits as a result of the NRC's review of the first three early site permit applications. The NRC also had the benefit of public meetings with external stakeholders on the development of NRC staff guidance on early site permits and combined licenses. The NRC

therefore decided that a substantial rewrite and expansion of the original proposed rulemaking to include changes throughout the entire body of NRC regulations in Title 10 Chapter 1 was desirable so that the agency may more effectively and efficiently implement the licensing and approval processes for nuclear power plants in Part 52.

Accordingly, the Commission decided to withdraw the July 2003 proposed rule in its entirety and develop a revised proposed rule for public comment. The revised proposed rule contains a reorganization and virtually complete rewriting of Part 52, and conforming changes throughout the NRC's regulations to improve the organization, format, and language of Part 52, and to clarify the applicability of various technical and regulatory requirements throughout Title 10 Chapter 1 to each of the processes in Part 52 (early site permit, standard design approval, standard design certification, combined license, and manufacturing license).

4. Identification and Discussion of the Alternative Approaches

4.1 Alternative 1 - Take No Action

The no-action alternative is not to revise 10 CFR Part 52 and not to make conforming changes throughout 10 CFR. This action would not support the original intent of the Commission to revisit and update the rulemaking after gaining some experience with its use. Since the promulgation of 10 CFR Part 52 in April 1989, the NRC has approved three design certifications, issued a final design approval for a fourth design, and began reviewing three early site permit applications. In addition, the Commission has held numerous public meetings to obtain input from stakeholders on the Part 52 regulatory processes.

The pros and cons of Alternative 1 are as follows:

Pros:

- The NRC would not incur the cost of the final rulemaking.

Cons:

- would not increase regulatory efficiency.
- would not reduce unnecessary regulatory burden.
- would not address issues and incorporate lessons learned from the Part 52 licensing processes.
- would not make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes.
- would not address errors identified since the promulgation of Part 52.
- would not clarify ambiguities in Part 52 to reflect the original intent of the NRC.

4.2 Alternative 2 - Publish Proposed Revisions to Part 52

Alternative 2 would reorganize and rewrite Part 52 to incorporate lessons learned about Part 52 licensing and regulatory processes from reviewing design certification and early site permit applications, and from interactions with stakeholders on Part 52, including the combined license process. This rewrite would include conforming changes throughout 10 CFR to reflect the adoption of licensing and regulatory- approval processes in Part 52 and to clarify the relationship between requirements in Part 52 and other regulatory requirements in the regulations. Although the rule is mainly focused on Part 52, the NRC is proposing changes in many other parts of the regulations to clarify ambiguities and maintain consistency between the various licensing processes.

The pros and cons of Alternative 2 are as follows:

Pros

- would increase regulatory efficiency
- would reduce unnecessary regulatory burden
- would address issues and incorporate lessons learned from the Part 52 licensing processes
- would make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes
- would address errors identified since the promulgation of Part 52
- would clarify ambiguities in Part 52 to reflect the original intent of the NRC

Cons

- NRC would incur the cost of the final rulemaking.

The proposed changes in this rulemaking can loosely be grouped in three categories, (i) conforming changes, format changes, reorganization and clarifications that do not impose additional regulatory requirements, (ii) corrections, omissions and additions that conform to the current NRC policy, and hence are not additional requirements, and (iii) changes that impose additional regulatory requirements that represent a departure from the current NRC policy. A regulatory analysis addresses only the incremental changes for measuring the impact of a rule. Accordingly, this regulatory analysis addresses the changes described in the last group (iii). The proposed rule contains four changes that represent a departure from the current NRC policy.

The four proposed changes that require further analysis are—

- (1) update emergency preparedness requirements for a COL applicant referencing an ESP,
- (2) change the manufacturing licensing process concept; and require the development of inspection, testing, analyses and acceptance criteria (ITAAC) for the manufacturing licensing

application,

(3) implement quality assurance requirements per 10 CFR Part 50, Appendix B, for ESP applicants, and

(4) implement reporting of defects requirements under Part 21 and Section 50.55(e) for referenced ESP applicants and design certification applicants.

Detailed discussion of these four proposed changes are described below:

4.2.1 Update emergency preparedness requirements for a COL Applicant referencing an ESP

This amendment pertains to a COL applicant referencing an ESP. It requires the applicant to update and correct emergency preparedness information of the site conditions and to discuss whether the new information may materially change the bases for compliance with the applicable NRC requirement. New information which materially changes the bases for compliance includes (1) information which substantially alters the bases for a previous NRC conclusion on the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, and (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions for emergency preparedness.

This amendment to update the ESP's emergency preparedness information and the corresponding discussion of bases of compliance in the combined license application constitutes a change from the existing rule. The detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.1.

4.2.2 Change the manufacturing licensing process concept, and require the development of ITAAC for the manufacturing license application

Appendix M of Part 52 currently sets forth the NRC's requirements for manufacturing licenses. Appendix M, which was first adopted by the NRC in 1973, provides for issuance of a license authorizing the manufacture of a nuclear power reactor to be incorporated into a nuclear power plant under a construction permit and operated under an operating license at a different location from the place of manufacture. Under the current licensing regime in Appendix M, the NRC does not approve a final reactor design to be manufactured before issuing the manufacturing license. Rather, as in the Part 50 two-step licensing process, the NRC issues a manufacturing license based upon the review of a preliminary design equivalent to that provided in a construction permit application. Upon approval of the preliminary design and associated information, the NRC issues a manufacturing license authorizing the manufacture—but not the removal from the manufacturing site—of one or more nuclear power reactors. Thereafter, manufacturing can begin, although the NRC must approve the final design of the manufactured reactor by license amendment.

In view of the substantial re-organization and rewriting of 10 CFR generally, the NRC has reconsidered the efficacy of the current manufacturing license process in Appendix M and proposes substantial changes to enhance regulatory effectiveness and efficiency. The most important change in the manufacturing license concept proposed by the NRC is that a final reactor design must be submitted and approved before issuance of a manufacturing license. This approval of a final reactor design eliminates one step from the current two-step process of issuing a manufacturing license, and amending the license when a final design is submitted. The technical information required to be included in an application for a manufacturing license, as set forth in proposed §§ 52.157 and 52.158, reflects both the expanded scope of approval to include the final design of the reactor to be manufactured, as well as lessons learned with respect to early site permits. Section 52.157 specifies the standard information required to be submitted in support of the design of a reactor. In addition, the application must address the

provisions with respect to the demonstration by test, analysis, experience or a combination thereof of simplified, inherent, passive, or other innovative means to accomplish safety functions, or the results of testing of a prototype plant, as set forth in proposed revisions to § 50.40. Information which must be submitted as part of an application, but is not typically considered part of a final safety analysis report, is identified in § 52.158. This includes a PRA, proposed ITAAC to be used by the licensee that will construct and operate a nuclear power plant at its site using the manufactured reactor, and an environmental report for the manufactured reactor. The environmental report must address severe accident mitigation design alternatives (SAMDA), since the design approval phase is usually the most cost-effective stage for incorporating design features for addressing severe accidents. The NRC is approving a reactor design for manufacture and the ITAAC for verifying that it has been acceptably manufactured and integrated into a nuclear power facility such that it can be safely operated in accordance with the approved manufactured reactor design, the NRC's regulations, and the requirements of the AEA. The proposed changes to the current Appendix M constitutes a change from the existing rule. The detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.2.

4.2.3 Implement quality assurance requirements per 10 CFR Part 50, Appendix B for ESP applicants

The current regulations do not explicitly require implementing a Part 50 Appendix B program in support of an ESP application, and there is no current requirement to describe the applicant's quality assurance program in an ESP application. However, under the current Part 52 regulatory process, activities associated with site safety must be controlled by QA measures sufficient to provide reasonable assurance that future safety-related systems, structures, and

components (SSC) of a nuclear power plant that might be constructed on the site will perform adequately in service. The regulations in 10 CFR 52.39, with certain specific exceptions, require the NRC to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a construction permit, operating license, or combined license. Because of this finality, conclusions made during the ESP phase will be relied upon for use in subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an ESP is issued. Therefore, the level of quality used to control activities related to safety-related SSCs should be equivalent in substance in the ESP and COL phases. For these reasons, applications must apply quality controls to each ESP activity associated with the generation of design information for safety-related SSCs that are equivalent to those specified in Appendix B for similar activities.

The proposed rulemaking eliminates this ambiguity by the explicit requirement for an ESP applicant to establish and use quality control processes in accordance with 10 CFR Part 50 Appendix B, to conduct activities associated with an ESP. This constitutes a change from the existing rule. A detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.3.

4.2.4 Implement reporting of defects requirements under Part 21 for ESP applicants and design certification applicants under Part 52

The reporting requirements in Section 206 of the Energy Reorganization Act of 1974 (ERA), as amended (1974 ERA) are incorporated in 10 CFR Part 21 and § 50.55(e). Section 50.55(e)

sets forth the Section 206 reporting requirements applicable to holders of a construction permit. The proposed rule sets forth the NRC's proposals on how reporting requirements to implement Section 206 should be applied to applicants for ESPs and design certifications.

The NRC believes that the extensions of NRC's reporting requirements implementing Section 206 of the ERA to Part 52 licensing and approval processes should be consistent with three key principles. First, the requirements should be legal obligations throughout the entire regulatory life of an NRC license, or a standard design certification. Second, defects must be reported whenever the information on potential defects will be most effective in ensuring the integrity and adequacy of the NRC's regulatory activities under Part 52 and the activities of entities subject to the Part 52 regulatory regime. Third, each entity conducting activities within the scope of Part 52 must develop and implement procedures and practices to ensure that it fulfills its Section 206 reporting obligations in an accurate and timely manner.

Reporting requirements for early site permits

The NRC proposes that Part 21 apply to early site permit applicants and holders. In order for the applicant for an early site permit to have the capability to report to the NRC any known significant safety concerns with respect to its site, or any safety concerns of which it may subsequently become aware (i.e., to be able to report any defects or failures associated with substantial safety hazards under part 21) the early site permit applicant would have to have a program in place for implementing the requirements of 10 CFR part 21. The applicant's program may be inspected by the NRC as part of the application review and approval of the early site permit application would be subject to approval of the part 21 program.

Reporting requirements for standard design certification

A standard design certification represents the NRC's approval by rulemaking of an acceptable nuclear power reactor design, which may then be referenced in a subsequent construction permit, operating license, combined license, or manufacturing license application. The NRC proposes to impose requirements to implement Section 206 on applicants for standard design certification.

5.1 Regulatory Impact —Cost-benefit of the proposed action

Discussion in Section 4.2 identified four changes that represent a departure from the current NRC policy. These changes would not affect any current licensees under Part 52 since no license has yet been issued under Part 52, and would be applicable to future applicants. The cost-benefit analysis of the regulatory requirements associated with these four changes are based upon the NRC's assessment of the future business scenario as described below.

- Eight COL applications during the next 3 years and thereafter two COL applications per year would be submitted over the next 17 years. It is assumed that half of those anticipated COL's would be referencing an ESP; i.e., $4 = (0.5 \times 8)$ COL applications would be referencing an ESP during the next 3 years, and $1 \text{ COL} = (2 \times 0.5)$ would be referencing an ESP annually for the next 17 years.
- 1 ESP application would be submitted over the next 3 years and thereafter one application would be submitted annually over the next 17 years.
- 4 design certifications would be submitted over the next 4 years.
- 2 manufacturing licenses would be submitted in the next 20 years.

5.1.1 Update emergency preparedness requirements for a COL applicant referencing an ESP

A combined license applicant referencing an early site permit must include an update of the emergency preparedness information and a discussion of whether the new information materially alters the basis for compliance with the relevant requirements. This additional requirement constitutes a change from the current rule. The cost-benefit analysis of this proposed amendment using the above mentioned assumptions is as follows:

Costs to Applicant

The NRC assumed that four COL applications referencing an ESP would be submitted over the next 3 years, and thereafter one COL application referencing an ESP would be submitted annually for the next 17 years.

The NRC estimates that it will take an applicant approximately 4 staff-months for a one-time cost of \$64 K (4 staff-months x 4 weeks/month x 40 hrs/week = 640 hr x \$100/hr) per application for updating the emergency preparedness information of an ESP.

The business scenario discussed above would result in a present value of approximately \$985 K at a 3-percent discount rate. With a 7-percent discount rate, the estimate would be \$685 K.

Costs to NRC

NRC would not incur additional costs for reviewing the updated emergency preparedness of a referenced early site permit, since the NRC would have to review the updated information anyway, particularly considering possibilities of significant lapse of time between the issuance of an ESP and the submittal of a COL.

Benefits to Applicant

The NRC believes that this proposed amendment would reduce the overall regulatory burden of an applicant referencing an early site permit when reviewed in the context of the entire license review process, even though inclusion of the updated emergency preparedness information in the referencing license application is an additional burden on the applicant. The NRC, in absence of the updated information, can not adequately assess the state of emergency preparedness of the COL application referencing an ESP. To determine the adequacy of the state of emergency preparedness, the NRC, would have to request the information of the applicant. The applicant would spend considerable more resources to compile, analyze and submit the information at a later date as compared to providing the information in the referencing application. This delayed submittal would also prolong the license review time. It is estimated that it will take at least 50 percent more effort to submit the information after issuance of the referencing license application, since the submittal would necessitate reassembly of the team, require review of the existing documents and then update potentially large number of changes to the original submittal.

Using the above business scenario, updating of the emergency preparedness information during the license review phase would increase the applicant's effort by 50 percent, or \$96 K (4 NRC-months x 4 weeks/month x 40 hr/week x 1.5= 960 hrs x \$100/hr) per application. The same business scenario, at a 3-percent discount rate would result in a present value of approximately \$1,478 K. With a 7-percent discount rate, the estimate would be \$1,028 K.

Benefits to NRC

The review of the submittal would have no additional impact on the NRC for the reasons discussed in the cost section, but the schedule delays might have an impact. No efforts have

made to quantify the impact of potential schedule delay.

5.1.2 Change in manufacturing licensing process concept and require the development of ITAAC for the manufacturing license application

This proposed amendment requires that a final reactor design be submitted and approved before issuance of a manufacturing license. The approval of a final reactor design eliminates the current two-step regulatory process of issuing a manufacturing license based on preliminary design information and amending the license when a final design is submitted. Approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources to manufacturing the reactor. The technical information that must be included in an application for a manufacturing license reflects both the expanded scope of approval to include the final design of the reactor to be manufactured and the lessons learned during the ESP applications reviews.

The proposed amendment would eliminate preparation and agency review of the preliminary license application, but would require an expanded license application that would include additional technical information, namely a PRA, proposed ITAAC to be used by the licensee that will construct and operate a nuclear power plant at the site using the manufactured reactor, and an environmental report. Under the current regulatory process, the PRA and the Environmental Report are integral parts of the license application, and hence inclusion of these in the final safety analysis report (FSAR), a part of the license application under the proposed rulemaking, though not typical, are not considered additional burden on the applicant. However, the development of ITAAC would be an additional burden. Under the proposed rulemaking elimination of the preliminary license application in itself would be a reduction in regulatory burden on both the applicant and the NRC.

The cost-benefit analysis of this proposed amendment is as follows:

Cost to Applicant

It is assumed that an application for a manufacturing license under the proposed rulemaking is equivalent to the first step of the existing process (i.e., license application and corresponding design report except for the development of ITAAC). In other words, the preparation of a manufacturing license application under the proposed rule would involve the same amount of work as for the first step under the existing regulatory regime except for developing ITAAC. The proposed requirement for developing ITAAC as a part of the manufacturing license application constitutes a change to the existing regulations and would impose additional regulatory burden on applicants for a manufacturing license.

Using the business scenario of two applications for manufacturing license, the NRC estimates that the applicant would incur a one time cost of \$4,160 K (10 staff-years x 2080 hr/year = 20,800 hr x \$ 100/hr x 2) applications for the development of ITAAC.

Cost to NRC

The NRC estimates that the agency would incur a one-time cost for reviewing the ITAAC \$625 K (2 staff-years x 1776 hr/year x \$ 88/hr x 2 applications).

Benefit to Applicant

The applicant would not be required to prepare and submit an amendment of a manufacturing license under the proposed rule, reduce regulatory burden compared to the two-step licensing process of the existing regulations. The NRC estimates that the elimination of one step would result in a one-time reduction of \$31,200 K (75 staff-years x 2080 hr/year x \$100/hr x 2 applications).

Benefit to NRC

The NRC estimates that the agency would avoid the one-time cost of reviewing the license application \$9,377 K (30 staff-years x 1776 hr/year x \$88/hr x 2 applications).

It should be noted, developing ITAAC adds burden for the manufacturing license applicant, it does not add burden to the ultimate operator of a nuclear power generating facility since the ITAAC are developed before the issuance of the operating license and included in the operating license costs. Put another way, the additional burden of ITTAC actually shifts the burden from one phase to another; i.e., from operating license phase to the manufacturing license phase.

5.1.3 Implement Quality Assurance (QA) requirements per 10 CFR Part 50, Appendix B for ESP applicants

The proposed rulemaking requires an ESP applicant to implement a QA program pursuant to Part 50 Appendix B to control ESP activities. The incremental burden of using Part 50 Appendix B program is shown below.

Costs to Applicant

The NRC estimates that the applicant would incur a one-time costs of establishing a Part 50 Appendix B QA program of \$48 K (3 staff-months x 4 weeks/month x 40 hr/week x \$100/hr) per applicant, and \$72 K (40 hr/month x 18 months x \$100/hr) per applicant to implement the QA program for the ESP activities or for a total of \$120 K per applicant.

Assuming the above business scenario of 1 ESP application in the next 3 years, and thereafter 1 ESP application per year for the next 17 years at a 3-percent discount rate would result in a present value of approximately \$1,518 K. With a 7-percent discount rate, the estimate would be

\$991 K.

Costs to NRC

The NRC would not incur any additional costs.

5.1.4 Implement reporting of defects requirements under Part 21 for ESP applicants and Design Certification applicants under Part 52

Part 21 implements the reporting requirements in Section 206 of the Energy Reorganization Act of 1974, as amended (1974 ERA). The proposed Part 52 rule sets forth the Commission's proposals for applying reporting requirements implementing Section 206 of the 1974 ERA be applied to Part 52 licensing processes. The NRC's three key principles of reporting under Section 206 of the ERA are (i) a legal obligation exists throughout the entire regulatory life of a NRC license or a Part 52 regulatory approval, (ii) defects should be reported whenever the information on potential defects would be most "effective", and (iii) each entity conducting activities within the scope of Part 52 should develop and implement procedures and practices to ensure that it accurately and timely meets its Section 206 reporting obligations.

This proposed amendment requires that applicants for ESPs, and standard design certifications make contractual agreements with contractors, subcontractors, consultants and other suppliers of goods and services to notify them that they are subject to the NRC's regulatory requirements for reporting and developing and implementing reporting requirements. These requirements would impose additional regulatory burden on applicants and their subcontractors, consultants, and other suppliers of goods and services.

Each entity conducting activities under Part 52, would have a quality assurance (QA) program in place to control their specific activities. The QA programs of applicants and their contractors, subcontractors, consultants, and other suppliers must be modified to include procedures and practices for timely and accurate reporting of any defects that they become aware of during and after completion of their scope of work. These programs must be capable of being implemented later when a product is referenced in a subsequent construction permit, an operating license, or a COL. The programs for reporting must also continue throughout the regulatory life of the referenced license. In addition, for holders of combined license and manufacturing licenses, the records regarding reporting of defects must be kept for the duration of the regulatory life. These requirements would impose additional regulatory burden on the future applicants.

The cost-benefit analysis of this proposed amendment is as shown below :

Costs to Applicant

ESP Applicants

The NRC estimates that the one-time cost for setting up the procedures for reporting of defects would be \$96 K (320 hr x 3 vendors x \$100/hr) per ESP applicant.

Per the business scenario assumption of 1 referenced ESP applicant during the next 3 years, thereafter 1 referenced ESP applicant annually for the next 17 years would occur. This would result, at a discount rate of 3-percent in a cost of \$1,214 K, and \$793 K at a discount rate of 7-percent.

Also, the NRC estimates that it would require 180 hr/year for an estimated three contractors to report defects and maintain records for the regulatory life of an ESP, and it is assumed that 4 ESP applicants would be affected for a cost \$216 K (180 hr/year x 3 vendors x \$100/hr x 4 ESP

applicant) annually for the next 20 years for a net present value of \$3,218 K at a 3-percent discount rate and \$2,290 K at a 7-percent discount rate.

Design Certification Applicants

In addition, 4 design certification applications during the next 4 years are estimated to be referenced by COL applicants. Setting up the procedures for reporting of defects would incur a one-time cost of \$96 K (320 hr x 3 vendors x \$100/hr) per applicant. Per the business scenario of 4 design certifications it would result in a net present value of \$341 K at a 3-percent discount rate \$ 293 K and at a discount rate of 7-percent.

Also, for 4 design certification applicants, it would cost \$216 K (180 hr/year x 3 vendors x \$100/hr x 4 applicants) annually for the next 16 years starting from the fourth year for a net present value of \$2,777 K at a 3-percent discount rate and \$1,747 K at a 7-percent discount rate.

In summary, at a 3-percent discount rate it would cost \$7,550 K (1,214+3,218+341+2,777), and \$5,123 K (793+2,290+293+1,747) at a 7-percent discount rate.

5.1.5 Final Rulemaking costs:

NRC

The NRC estimates that completing the final rulemaking would require a one-time cost of \$328 K (2.1 staff-years x 1776 hr/year x \$ 88/hr).

5.2 Aggregate Analysis

In accordance with the RA Guidelines, an aggregate analysis of all the significant provisions is shown in table below.

Provisions	Impact Type	Monetary Impact	
		Applicant	NRC
		All Costs in Thousand \$'s	
		3%/7% @	3%/7% @
(1) Update of emergency preparedness for an ESP	Costs	-985/-685	0
	Savings	1,478/1,028	0
(2) Manufacturing license concept change, & development of ITAAC	Costs	-4,160/-4,160*	-625/-625*
	Savings	31,200/31,200*	9,377/9,377*
(3) Implement QA program for ESP applicant	Costs	-1518/-991	0
	Savings	0	0
(4) Implement reporting of defects (Part 21)	Costs	-7,550/-5,123	0
	Savings	0	
Total Part 21 amendments		-7,550/-5,123	0
Total Part 52 rulemaking amendments		26,015/26,392	8,752/8,752*
Total All Parts rulemaking amendments		18,465/21,269*	8,752/8,752*
NRC Final rulemaking Cost	Costs	0	-328/328*
Net monetary impact at (3%/7% discount rate)		26,889/29,693	

Costs are negative, savings are positive.

@ Discount Rate

* Indicates One-time Occurrence

5.3 Disaggregation Analysis

The NRC has prepared an analysis of the impact of the proposed changes (Attachment A) that identifies each provision affected by the rulemaking and determines whether it is appropriate to include each proposed change in the rule. This attachment details an analysis of each proposed change and whether it is needed for the regulatory initiative to resolve the concerns and meet the stated objectives that are the focus of the regulatory initiative. The NRC also performed an analysis to identify any individual provision that could impose cost disproportionate to the benefits attributable to each provision. The NRC has concluded that there are no provision whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could mask the impact of this rulemaking.

6. Decision Rationale

The NRC proposes to adopt Alternative 2. The basis for this proposed rulemaking is regulatory efficiency. Alternative 2 meets the objectives as stated in the Section 1- Statement of Objectives. A few salient features of the objectives are cited below.

Regulatory efficiency

- The regulatory requirements for license applications and supporting documents have been organized for consistency between the various licensing and regulatory processes of 10 CFR Part 52.
- The interconnection with other parts of Title 10 Chapter 1 are clearly described.
- Regulatory requirements for information for regulatory approval are clearly expressed enabling applicants to address relevant issues completely, and provide sufficient

information in license application and avoiding burdensome and costly resubmittals of information during the license review.

Reduction of unnecessary regulatory burden

- Regulatory burden reduction of \$26,295 K at a 3-percent discount rate and \$29,164 K at a 7-percent discount rate

Address issues and lessons learned with respect to the Part 52 licensing process:

- Applicants resolve design development issues early in the process ensuring early considerations and resolution of technical matters before a substantial commitment of resources.
- Increases regulatory stability and predictability, saving resources.
- Facilitates regulatory process of standardization of nuclear power plants.

Make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes.

Address errors identified since the promulgation of Part 52.

Clarify ambiguities in Part 52 to reflect the original intent of the NRC.

7. Implementation Schedule

This rule will become effective 30 days after publication of the final rule in the *Federal Register*.

Attachment A

Disaggregation Analysis

Section/Description	RE	RB	LL	CC	OR	CA
10 CFR Part 1						
1.4.3 Office of nuclear reactor regulation				X		
10 CFR Part 2						
Subpart A						
2.1 Scope				X		
2.4 Definitions				X		
2.100 Scope of parts				X		
2.101 Filing of applications	X			X		X
2.102 Administrative review of application				X		
2.104 Notice of hearing	X			X		
2.105 Notice of proposed action	X			X		
2.106 Notice of issuances				X		
2.109 Effect of timely renewal application	X			X		
2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues				X		
2.111 Prohibition of sex discrimination				X		
Subpart B						
2.2 Scope of subpart				X		
2.202 Orders	X			X		
Subpart C						
2.390 Public inspections, exemptions, requests for withholding				X		
Subpart E						
2.500 Scope of subpart				X		
2.501 Notice of hearing on application pursuant to subpart F of part 52 for a license to manufacture nuclear power reactors	X	X		X		
2.502 Notice of hearing on application under a construction permit for nuclear power reactor manufactured at the site at which the reactor to be operated- Deleted	X	X		X		
2.503 Finality of decision	X	X		X		
2.504 Applicability of other sections				X		
Subpart H						
2.800 Scope and applicability	X			X		X
2.801 Initiation of rulemaking	X			X		X

Legend: RE - Increase Regulatory Efficiency; RB - Reduce Regulatory Burden; LL - Lesson Learned; CC - Conforming Changes throughout 10 CFR; OR - Correct Omissions and Error; CA - Clarify Ambiguous Language

Section/Description	RE	RB	LL	CC	OR	CA
2.811 Filing of standard design certification application; required copies	X			X		X
2.813 Written communications	X			X		X
2.815 Docketing and acceptance review	X			X		X
2.817 Withdrawal of application				X		X
2.819 Denial of application for failure to supply information	X			X		X
10 CFR Part 10						
10.1 Purpose				X		
10.2 Scope				X		
10 CFR Part 19						
19.1 Purpose				X		
19.2 Scope	X			X		
19.3 Definition	X			X		
19.11 Posting of notices to workers	X			X		X
19.14 Presence of representatives of licensees and regulated entities, and workers during inspections	X			X		X
19.20 Employee protection				X		
19.31 Application for exemptions				X		
19.32 Discrimination prohibited				X		
10 CFR Part 20						
20.1002 Scope				X		
20.1401 General provisions and scope-Deleted				X		
20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits				X		
10 CFR Part 21						
21.2 Scope				X		
21.3 Definitions			X	X		
21.5 Communications				X		
21.21 Notification of failure to comply or existence of a defect and its evaluation				X		
21.51 Maintenance and inspections of records	X		X	X		
21.61 Failure to notify	X		X	X		
10 CFR Part 25						
25.35 Classified visits				X		
25.5 Definitions				X		
10 CFR Part 26						
26.2 Scope				X		
26.10 General performance objectives				X		
10 CFR Part 50						
50.2 Definitions	X		X	X		X
50.10 License required	X		X	X		X

Legend: RE - Increase Regulatory Efficiency; RB - Reduce Regulatory Burden; LL - Lesson Learned; CC - Conforming Changes throughout 10 CFR; OR - Correct Omissions and Error; CA - Clarify Ambiguous Language

Section/Description	RE	RB	LL	CC	OR	CA
50.23 Construction permits				X		
50.30 Filing of application; oath or affirmation	X			X		
50.33 Contents of applications; general information.	X			X	X	
50.34 Contents of construction permits and operating license applications; technical information	X			X	X	X
50.34a Design objectives for equipment to control releases of radioactive material in effluents - nuclear power reactors				X		
50.36a Technical Specifications on effluents from nuclear power reactors	X		X	X		
50.37 Agreement limiting access to classified information				X		
50.40 Common standards	X			X		
50.43 Additional standards and provisions affecting class 103 licenses for commercial power	X			X		
50.45 Standards for construction permit, combined operating license				X		
50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors				X		
50.47 Emergency plans	X		X	X		X
50.48 Fire protection				X		
50.49 Environmental qualification of electric equipment important to safety for nuclear power plants				X		
50.54 Conditions of licenses	X		X	X		
50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses	X		X	X		X
50.55a Codes and standards				X		
50.59 Changes, tests, and experiments				X		
50.61 Fracture toughness requirements for protection against pressurized thermal shock events				X		
50.63 Loss of all alternating current power				X		
50.65 Requirements for monitoring effectiveness of maintenance at nuclear power plants				X		
50.70 Inspections applicability to early site permit holders				X		
50.71 Maintenance of records, making of reports	X			X		
Section/Description	RE	RB	LL	CC	OR	CA
50.73 License event report system				X		

Legend: RE - Increase Regulatory Efficiency; RB - Reduce Regulatory Burden; LL - Lesson Learned; CC - Conforming Changes throughout 10 CFR; OR - Correct Omissions and Error; CA - Clarify Ambiguous Language

Section/Description	RE	RB	LL	CC	OR	CA
50.75 Decommissioning funding assurance		X		X		
50.78 Installation information and verification				X		
50.80 Transfer of license				X		
50.81 Creditor regulations				X		
50.90 Application for amendment of license or construction permit				X		
50.91 Notice for public comment; state consultation				X		
50.92 Issuance of amendment				X		
50.100 Revocation, suspension, modification of licenses, permits, and approvals for cause				X		
50.109 Backfitting				X		
50.120 Training and qualification of nuclear power plant personnel	X			X		
Appendix A to Part 50-general design criteria-nuclear power plants				X		
Appendix B to Part 50-Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	X		X	X		X
Appendix C to Part 50-A guide for the financial data and related information required to establish financial qualifications for construction permits and combined licenses				X		
Appendix E to Part 50- Emergency planning and preparedness for production & utilization facilities	X		X	X		X
Appendix I to Part 50- Numerical guides for design objectives and limiting conditions for operation to use the criterion "As low as is reasonably achievable" for radioactive material in nuclear light-water-cooled nuclear power reactors effluents				X		
Appendix J to Part 50-Primary reactor containment leakage testing for water-cooled reactors				X		
Appendices M and O to Part 50-Moved to Part 52				X		
Appendices S to Part 50- Earthquake Engineering Criteria for Nuclear power plants				X		
10 CFR Part 51						
51.17 Deleted				X		
51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements	X			X		
51.22 Criteria for categorical exclusion	X		X	X		
51.23 Temporary storage of spent fuel after cessation of reactor operation-generic determination of no significant environmental impact				X		

Legend: RE - Increase Regulatory Efficiency; RB - Reduce Regulatory Burden; LL - Lesson Learned; CC - Conforming Changes throughout 10 CFR; OR - Correct Omissions and Error; CA - Clarify Ambiguous Language

Section/Description	RE	RB	LL	CC	OR	CA
51.30 Environmental assessment	X	X		X		
51.31 Determinations based upon environmental assessment.	X	X	X	X		
51.32 Finding of no significant impact	X	X	X	X		
51.45 Environmental report	X		X	X		
51.50 Environmental report -construction permit, early site permit, or combined license stage	X		X	X		
51.51 Uranium fuel cycle environmental data - Table S				X		
51.52 Environmental effects of transportation of fuel and waste-Table S-4.				X		
51.53 Post construction environmental reports	X			X		
51.54 Environmental report-manufacturing license	X	X		X		
51.55 Environmental report-design certification	X		X	X		
51.58 Environmental report-number of copies; distribution	X			X		
51.66 Deleted				X		
51.71 Draft environmental impact statement-contents	X			X		
51.75 Draft environmental impact statement-construction permit, early site permit, or combined license				X		
51.95 Deleted	X			X		
51.105 Public hearings in proceedings for issuance of construction permits or early site permits	X	X	X	X		
51.105a Public hearings in proceedings for issuance of manufacturing licenses	X	X		X		
51.108 Deleted	X		X	X		
10 CFR Part 52						
52.0 Scope; applicability of 10 CFR Chapter 1 provisions	X		X	X		X
52.1 Definitions	X		X	X	X	
52.2 Interpretations	X			X		
52.3 Written communications				X		
52.4 Deliberate misconduct	X			X		
52.7 Specific exemptions	X			X		
52.8 Combining licenses	X			X		
52.9 Jurisdictional limits	X			X		
52.10 Attacks and destructive acts	X			X		
52.10a Information collection requirements-OMB Approval				X		
Subpart A Early Site Permits						
52.11 Scope of subpart				X		
52.13 Relationship to other subparts	X			X		X

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Section/Description	RE	RB	LL	CC	OR	CA
52.15 Filing of application	X		X	X		X
52.16 Contents of application-general information	X			X		
52.17 Contents of application-technical information	X		X	X	X	X
52.18 Standard for review of application	X			X		
52.21 Administrative review of application; hearings				X		
52.24 Issuance of early site permits	X		X	X		
52.25 Extent of activities permitted	X			X		
52.28 Transfer of early site permits	X		X			
52.29 Application for renewal					X	
52.31 Criteria for renewal	X				X	
52.39 Finality of early site permit determination	X			X		
Subpart B Standard Design Certification						
52.41 Scope	X			X		
52.43 Relationship to Others	X		X	X		
52.45 Filing of application	X		X	X		X
52.46 Contents of application; general information	X			X		
52.47 Contents of application; technical information	X		X			X
52.48 Standards for review of applications	X		X			X
52.54 Issuance of standard design certification	X		X			X
52.59 Criteria for renewal	X				X	
52.63 Finality of standard design certifications	X	X			X	
Subpart C Combined License						
52.73 Relationship to other subparts	X			X		
52.77 Contents of application; general information	X				X	
52.79 Contents of applications; technical information in final safety analysis report	X		X		X	X
52.83 Finality of referenced NRC approvals	X		X			X
52.85 Administrative review of applications; hearings	X					
52.87 Referral to the ACRS						
52.89 Environmental review- deleted & reserved	X					X
52.91 Authorization to conduct site activities	X					
52.97 Issuance of combined licenses.			X			
52.98 Finality of combined license; information requests.	X					
52.99 Inspection during construction.	X					X
52.103 Operation under a combined license	X					X
52.104 Duration of combined license	X					
52.105 Transfer of combined license	X					
52.107 Application for renewal	X					

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Section/Description	RE	RB	LL	CC	OR	CA
52.109 Continuation of combined license	X					
52.110 Termination of license	X					
Subpart E Standard Design Approvals						
52.131 Scope of subpart	X					
52.133 Relationship to other subparts	X					
52.135 Filling of applications	X					
52.136 Contents of application; general information	X					
52.137 Contents of application; technical information	X					X
52.139 Standards for review of applications	X					X
52.141 Referral to the ACRS	X					
52.143 Staff approval of design	X					
52.145 Finality of the design approval	X					X
52.147 Duration of design approval	X					
Subpart F- Manufacturing Licenses						
52.151 Scope of subpart	X					
52.153 Relationship to other subparts	X					
52.155 Filling of applications	X	X				
52.156 Contents of applications; general information	X	X				
52.157 Contents of applications; technical information	X	X				
52.157 Contents of applications; technical information in FSAR	X					
52.163 Administrative review of applications; hearings	X					
52.165 Referral to the ACRS	X					
52.167 Issuance of manufacturing license	X					
52.171 Finality of the manufacturing license; information requests	X	X				
52.173 Duration of manufacturing license	X					
52.175 Transfer of manufacturing license	X					
52.177 Application for renewal	X					
52.179 Criteria for renewal	X					
52.181 Duration of renewal	X					
Subpart H- Violations						
52.301 Violations				X		
52.303 Criminal penalties				X		
Appendices A,B & C Design Certifications for ABWR, System 80+, and AP600	X			X	X	X
Appendix O -Moved processes of Appendix O to Subpart E.				X		

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Section/Description	RE	RB	LL	CC	OR	CA
Appendix M- Moved Processes of Appendix M to Subpart F				X		
10 CFR Part 54						
54.1 Purpose				X		
54.3 Definition				X		
54.17 Filing of application				X		
54.31 Issuance of review license				X		
54.37 Additional records and record keeping requirement				X		
54.35 Requirements during term of renewed license				X		
10 CFR Part 55						
55.1 Purpose				X		
55.2 Scope				X		
55.5 Communication				X		
10 CFR Part 72						
72.210 General license required				X		
72.218 Termination of license				X		
10 CFR Part 73						
73.1 Purpose and scope				X		
73.50 Requirements for physical protection of licensed activities				X		
73.56 Personnel access authorization requirements for nuclear power plants				X		
73.57 Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to safeguards information by power reactor licensees.				X		
Appendix C				X		
10 CFR Part 75						
75.6 Maintenance of record and delivery of information, report, and other comments				X	X	
10 CFR Part 95						
95.5 Definition				X		
95.13 Maintenance of records				X		
95.19 Changes to security practices				X		
95.20 Grant, denial, or termination of facility clearance				X		
95.23 Termination of facility clearance				X		
95.31 Protective personnel				X		
95.33 Security education				X		
95.34 Control of visitors				X		
95.35 Access to matters classified as national security information and restricted data				X		

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Section/Description	RE	RB	LL	CC	OR	CA
95.36 Access by representatives of the international atomic energy commission or participants in other international agreements				X		
95.37 Classification and preparation of documents				X		
95.39 External transmission of documents and material				X		
95.43 Authorized to reproduce				X		
95.45 Changes in classification				X		
95.49 Security of automatic data processing systems				X		
95.51 Retrieval of classified material following suspension or revocation of access authorization				X		
95.53 Termination of facility clearance				X		
95.57 Reports				X		
95.59 Inspections				X		
10 CFR Part 140				X		
140.2 Scope				X	X	
140.10 Scope				X		
140.11 Amounts of financial protection for certain reactors				X		
140.12 Amount of financial protection required for other reactors				X		
140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under Part 52.				X		
140.20 Indemnity agreements and liens				X		
140.31 Scope				X		
140.93 Appendix C				X		
140.96 Appendix F				X		
10 CFR Part 170				X		
170.2 Scope				X		

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