NUCLEAR REGULATORY COMMISSION

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RIN 3150–AG24

Licenses, Certifications, and Approvals for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

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

DATES: The effective date is September 27, 2007.

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I. Background

A. Development of Proposed Rule

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 This proposed rule superseded the July 3, 2003, proposed rule.

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

The NRC planned to update 10 CFR part 52 after using the standard design certification process. The proposed rulemaking action began with the issuance of SECY–98–282, "Part 52 Rulemaking Plan," on December 4, 1998. The Commission issued a staff requirements memorandum (SRM) on January 14, 1999 (SRM on SECY–98–282), approving the NRC staff's plan for revising 10 CFR part 52. Subsequently, the NRC obtained considerable stakeholder comment on its planned action, conducted three public meetings on the proposed rulemaking, and twice posted draft rule language on the NRC's rulemaking Web site before issuance of the July 2003 proposed rule.

B. Publication of Revised Proposed Rule

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

Accordingly, the Commission decided to revise the July 2003 proposed rule and published a revised proposed rule for public comment on March 13, 2006. This revised proposed rule contained a rewrite of part 52, as well as changes throughout the NRC's regulations, to ensure that all licensing and approval processes in part 52 are addressed, and to clarify the applicability of various requirements to each of the processes in part 52. In light of the substantial rewrite of the July 2003 proposed rule, the expansion of the scope of the rulemaking, and the NRC's decision to publish the revised proposed rule for public comment, the NRC decided that developing responses to comments received on the July 2003 proposed rule would not be an effective use of agency resources. The NRC requested that commenters on the July 2003 proposed rule who believed that their earlier

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comments were not adequately addressed in the March 2006 proposed rule resubmit their comments.

II. Overview of Public Comments

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

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

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

The language did not explicitly identify the part 50 requirements that are "technically relevant to the design." Even where a specific regulation in part 50 is identified as a requirement, the language of the referenced regulation itself was not changed to reflect the specific requirements as applied to the part 52 processes. For example, § 52.79(b) provides that the application must contain the "technically relevant information required of applicants for an operating license required by 10 CFR 50.34." Other than the fact that this language shares the problem discussed earlier of what constitutes a "technically relevant" requirement, § 50.34(b) is based upon the two-step licensing process whereby certain important information is submitted at the construction permit stage, and then supplemented with more detailed information at the operating license stage. Thus, it could be asserted that certain information that must be submitted in the construction permit application, e.g., the "principal design criteria for the facility" required by § 50.34(a)(3)(i), may be regarded as not required to be submitted for a combined license application under the former version of part 52.

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

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

Accordingly, in the March 13, 2006, proposed rule the NRC took a more comprehensive approach to addressing these issues by reorganizing part 52, implementing a uniform format and content for each of the subparts in part 52, using consistent wording and organization of sections in each of the subparts, and making conforming changes throughout 10 CFR Chapter I to reflect the licensing and approval processes in part 52. The NRC also coordinated and reconciled differences in wording among provisions in parts 2, 50, 51, and 52 to provide consistent terminology throughout all of the regulations affecting part 52. Under the NRC's reorganization of part 52, the existing appendices O and M on standard design approvals and manufacturing licenses, respectively, have been redesignated as new subparts in part 52. Redesignating these appendices as subparts in part 52 has resulted in a consistent format and organization of the requirements applicable to each of the licensing and approval processes. In addition, the redesignation clarifies that each of the licensing and approval processes in these appendices are available to potential applicants as an alternative to the processes in part 50 (construction permit and operating license) and the existing subparts A through C of part 52. The Commission does not, by virtue of this redesignation, either favor or disfavor the processes in the former appendices M and O of part 52. Rather, the Commission is standardizing the format and organization of part 52, and clarifying the full range of alternatives that are available under part 52 for use by potential applicants. Consistent with the broad scope of part 52, the NRC has retitled 10 CFR part 52 as "Licenses, Certifications, and Approvals for Nuclear Power Plants."

The NRC has also reorganized and expanded the scope of the administrative and general regulatory provisions that precede the part 52 subparts by adding new sections on written communications (analogous to § 50.4), employee protection (analogous to § 50.7), completeness and accuracy of information (analogous to § 50.9), exemptions (analogous to § 50.12), combining licenses (analogous to

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§ 50.52), jurisdictional limits (analogous to § 50.53), and attacks and destructive acts (analogous to § 50.13). The NRC believes that adding the new sections to part 52 rather than revising the comparable sections in part 50 is more consistent with the general format and content of the Commission's regulations in each of the parts of Title 10. The NRC considered whether the numbering of the newly-added sections to part 52—in particular, the provisions on deliberate misconduct, employee protection, and completeness and accuracy of information—should match the numbering of the comparable sections in part 50. While this may have some benefit, the NRC ultimately decided not to adopt such a course for several reasons. First, other parts of the NRC's regulations in 10 CFR Chapter I do not maintain the same numbering scheme. Rather, it appears that the NRC attempted to maintain the order in which these sections are listed in each part. Second, there are other provisions in part 50 for which a comparable provision needed to be added to the general and administrative provisions in part 52, but for which it would be impossible to maintain the same numbering (for example, § 50.13 (attacks and destructive acts); § 50.32 (elimination of repetition); § 50.52 (combining licenses)), unless the substantive provisions of part 52, beginning with § 52.12, were changed.[1] Maintaining in part 52 the numbering scheme for some, but not all, comparable sections from part 50 ultimately would be viewed as haphazard and arbitrary. Finally, the NRC does not believe that external stakeholders who must constantly refer to part 52 will be confused by any difference in numbering of the three sections, given that there are other comparable provisions for which the numbering is necessarily different between parts 50 and 52. For these reasons, the NRC did not attempt to match in the final part 52 rule the numbering of the comparable sections in part 50.

Appendix N, which addresses duplicate design licenses, has been retained in both part 52 and part 50 to afford future applicants flexibility and to retain the possibility of achieving regulatory efficiencies in part 52 combined license proceedings. Since the preparation of the March 2006 proposed rule, several industry groups have announced their intention to seek combined licenses utilizing the same design. In view of this industry development, the NRC believes that there is potential utility to keeping the option of appendix N open to potential combined license applicants. Accordingly, the NRC is retaining in part 52 the procedural alternative provided in appendix N, and revising its language to make its provisions applicable to combined licenses using identical designs. Appendix Q, which addresses early staff review of site suitability issues, is being 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 the apparent redundancy between the early review of site suitability issues and the early site permit process. Accordingly, the NRC is removing appendix Q from part 52 and retaining it only in part 50.

Inasmuch as the NRC may, in the future, adopt other regulatory processes for nuclear power plants, the NRC has reserved several subparts in part 52 to accommodate additional licensing processes that may be adopted by the NRC. The NRC used a standard format and content for revising the regulations in the existing subparts and developing the new subparts that address the former appendices M and O. The standard format and content was modeled on the existing organization and content of subparts A and C. Appendix N of part 52, however, has not been revised in that fashion because of time constraints in developing the final rule.

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

To highlight the relationship between the requirements in part 52 of this final rule and the requirements in existing part 52, the NRC is making two cross-reference tables available to the public. These tables can be found on NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML062550U0246. Table 1 matches each part 52 requirement in this final rule with its counterpart in the existing rule. Table 2 is a reverse cross-reference table which identifies the section of the existing part 52 requirements from which each part 52 requirement in this final rule was derived.

IV. Responses to Specific Requests for Comments

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

Question 1: General Provisions. Create new subpart for part 50. In response to several commenters' concerns about the clarity of the applicability of part 50 provisions to part 52, the Commission has added provisions to part 52 (§§ 52.0 through 52.11) that are analogues to comparable provisions in part 50. Another possible way of addressing the commenters' concerns would be to transfer all the provisions in part 52 to a new subpart (e.g., subpart M) of part 50, and retain the existing numbering sequence for the current part 52 with the addition of a prefix (e.g., proposed

[1] The NRC notes, in this regard that nuclear industry stakeholders adversely commented on the revised numbering scheme as set forth in the 2003 proposed part 52 rule. They suggested that the NRC retain, to the greatest extent posible, the numbering of the then existing part 52. Inasmuch as § 52.12 is the first substantive provision of the former party 52, this placed an upper bound on the number of sections available for general provisions—that is § 52.0 through 52.11.

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50.1001 = current 52.1). The Commission is considering adopting this alternative proposal in the final rule and is interested in whether stakeholders regard this as a more desirable approach for minimizing the ambiguity of the relationship between part 50 and part 52.

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

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

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

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

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

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

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

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

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

Question 3: As indicated in Section IV, *Discussion of Substantive Changes* (in the March 13, 2006, proposed rule), the NRC is proposing to remove appendix Q to part 52 entirely from part 52 and retain it in part 50. Currently, appendix Q to part 52 provides for NRC staff issuance of a staff site report on site suitability issues with respect to a specific site, for which a person (most likely a potential applicant for a construction permit or combined license) seeks the NRC staff's views. The NRC is also considering removing, in the final rule, the early site review process in appendix Q to part 52 in its entirety from the NRC's regulations and is interested in stakeholder feedback on this alternative. One possible reason for removing the early site review process in its entirety is that potential nuclear power plant applicants would use the early site permit process in subpart A of part 52, rather than the early site review process as it currently exists in appendix Q to parts 50 and 52. Also, in cases where a combined license applicant was interested in seeking NRC staff review of selected site suitability issues (as appendix Q to part 52 was designed for), the applicant could request a pre-application review of these issues. The use of pre-application reviews for selected issues has been successfully used by applicants for design certification. The NRC is

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especially interested in the views of potential applicants for nuclear power plant construction permits and combined licenses as to whether there is any value in retaining the early site review process.

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

NRC Response: After considering these comments the NRC has decided to go forward with removal of appendix Q from part 52 in the final rule.

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

Question 4: Under subpart F of part 52 of the proposed rule, the NRC proposes to require approval of, and extend finality to, the final design for a reactor to be manufactured under a manufacturing license. While the NRC will also review the acceptability of the manufacturing license applicant's organization responsible for design and manufacturing, as well as the quality assurance (QA) program for design and manufacturing, the proposed rule does not provide a regulatory structure for further extending the scope of NRC review and issue finality to the manufacturing process itself. The NRC is considering extending regulatory review approval, and consequently expand issue finality, to the manufacturing itself in the final rule. There are two models that the Commission is considering adopting if it were to move in this direction. The first would be an analogue to the subpart C of part 52 combined license process, whereby the NRC would review and approve manufacturing ITAAC to be included in the manufacturing license. During the manufacturing of each reactor, the NRC would verify at the manufacturing location whether the ITAAC have been conducted and the acceptance criteria met. A NRC finding of successful completion of all the ITAAC would preclude any further inspection of the acceptability of the manufacture of the reactor at the site where the manufactured reactor is to be permanently sited and operated. The NRC's inspections and findings for the combined license or operating license would be limited to whether the reactor had been emplaced in undamaged condition (or damage had been appropriately repaired) and all interface requirements specified in the manufacturing license had been met. The NRC believes that it has authority to issue a manufacturing license under Section 161.h of the AEA.

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

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

Commenters' Response: Some commenters requested that applicants for manufacturing licenses be allowed, but not required, to use ITAAC to ensure that an "as-manufactured plant conforms to the important design characteristics specified in the application for the manufacturing license." Some commenters stated that a manufacturing license for evolutionary designs should be subject to proposed § 50.43(e) and should not require a prototype. Some commenters stated that manufacturing licenses should not be subject to more stringent requirements than design certifications.

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

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petition which demonstrated near-term interest in an application for a manufacturing license.

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

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

Commenters' Response: Some commenters stated the deletion of provisions allowing a construction permit applicant to reference an ESP or DC was ill-advised given the untested nature of the COL process and the resulting need to retain "regulatory flexibility" to deal with unexpected issues. As a contingency plan to buffer against difficulties with COL process, the commenters proposed the addition of a provision in part 50 to specify that a construction permit applicant could reference a DC without the inclusion of ITAAC. The commenters suggested that in these instances, "the operating license proceeding would need to find under 10 CFR 50.57(a)(1) that construction of the facility has been substantially completed, in conformity with the construction permit and the application as amended, the provisions of the Act, and the rules and regulations of the Commission." Commenters stated that standard design should be final and not open to review in the construction permit and operating licenses proceeding. Commenters requested a construction permit applicant be able to reference an ESP in the same way as would a COL applicant.

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

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

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

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

Question 7: As discussed in Section IV.C.6.f of the March 13, 2006, proposed rule, the NRC is proposing to modify § 52.79(a) to add requirements for descriptions of operational programs that need to be included in the final safety analysis report (FSAR) to allow a reasonable assurance finding of acceptability. This proposed amendment is in support of the Commission's direction to the staff in SRM–SECY–02–0067 dated September 11, 2002, "Inspections, Tests, Analyses, and Acceptance Criteria for Operational

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Programs (Programmatic ITAAC)," that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application. In this SRM, the Commission stated:

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

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

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

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

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

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

NRC Response: The NRC has decided to revise § 50.109 to include the conforming changes necessary to reflect part 52, rather than adopting a backfitting provision in part 52, because no commenter favored the alternative approach of adopting a backfitting provision in part 52, and both approaches are legally equivalent.

Question 9: The Commission is considering adopting in the final part 52 rulemaking an alternative to the re-proposed rule's approach for addressing new and significant environmental information with respect to matters addressed in the ESP environmental impact statement (EIS) which require supplementation.[2] As a separate matter, the Commission is also considering adopting in the final part 52 rulemaking an analogous requirement for addressing new information necessary to update and correct the emergency plan approved by the ESP, the ITAAC associated with EP, or the terms and conditions of the ESP with respect to emergency preparedness, or new information materially changing the Commission's determinations on emergency preparedness matters previously resolved in the ESP. To implement either or both of these alternatives, the Commission is also evaluating whether several additional concepts should be adopted in the final rulemaking. The two alternatives, as well as the additional implementing concepts, are described below. The Commission emphasizes that it may, with respect to the alternative addressing updating environmental information and emergency preparedness information, adopt either or both alternatives in the final part 52

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

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rulemaking, in place of or in addition to the proposed rule's alternative of conducting the updating in each combined license proceeding. Under the option where multiple alternatives for updating environmental and emergency preparedness information would be allowed, the Commission proposes that the decision be left to the combined license applicant as to which alternative to pursue. Commenters are requested to address: (1) the advantages and disadvantages of adopting each alternative for updating environmental and emergency preparedness information in an ESP proceeding as opposed to the proposed rule's alternative of conducting the updating in each combined license proceeding; (2) whether the Commission should only allow updating of environmental and emergency preparedness information in an ESP proceeding or in a COL proceeding, but not both; and (3) if the Commission allows updating in either an ESP proceeding or in a COL proceeding, whether it should be an option for the COL applicant to decide which update process to pursue. The Commission believes it may allow COL applicants the option of deciding whether to update environmental and emergency preparedness information in either an ESP proceeding or in a COL proceeding in order to afford the COL applicant the determination which approach best satisfies their business and economic interests.

Environmental Matters Resolved in ESP

The Commission is considering requiring a combined license applicant planning to reference an ESP to submit a supplemental environmental report for the ESP. The supplemental environmental report must address whether there is any new and significant environmental information with respect to the environmental matters addressed in the ESP EIS. Based upon this information, the NRC will prepare a draft supplemental environmental assessment (EA) or EIS setting forth the agency's proposed determinations with respect to any new and significant information. In accordance with existing practice and procedure, the draft supplemental EA or EIS will be issued for public comment. After considering comments received from the public and relevant Federal and State agencies, the NRC will issue a final supplemental EA or EIS. Once the final supplemental EA or EIS is issued, the ESP finality provisions in proposed § 52.39 would apply to the matters addressed in the supplemental EA or EIS, and those matters need not be addressed in any combined license proceeding referencing the ESP. Thus, for example, if a new and significant environmental issue, for example, a newly-designated endangered species, is addressed in the supplemental ESP EIS, the matter would be resolved for all combined licenses referencing the ESP (unless, of course, there is new and significant information identified at the time of a subsequent referencing combined license with respect to that endangered species). There would be no updating of environmental information necessary in the combined license proceeding. The Commission considers this approach for updating the ESP as meeting the Agency's obligations under the National Environmental Policy Act (NEPA), without imposing undue burden on the ESP holder and the NRC through continuous or periodic updating, and preserving the distinction between the ESP and any referencing combined license proceeding. Since an ESP may be referenced more than once, this approach would provide for issue finality of the updated information and preclude the need for reconsideration of the same environmental issue in successive combined license proceedings referencing the ESP. The Commission requests public comment on this proposal, which would likely involve changes to §§ 52.39, 51.50(c), 51.75, and 51.107 (and possibly conforming changes in parts 2, 51, and 52).

Emergency Preparedness Information Resolved in ESP

The Commission is separately considering requiring a combined license applicant referencing an ESP to provide to the NRC new EP information necessary to correct inaccurate information in the ESP emergency plan, EP ITAAC, or the terms and conditions of the ESP with respect to EP. Based upon the EP information submitted by the combined license applicant, the NRC will, as necessary, approve changes to the ESP emergency plan, the EP ITAAC, or the terms and conditions of the ESP with respect to EP. Once the Commission has resolved the EP updating matters, these matters would be accorded finality under § 52.39. There would be no separate updating necessary in the combined license proceeding. Thus, for example, if an EP ITAAC in an ESP were changed by virtue of this updating process, the changed ITAAC for EP would be applicable to any combined license referencing the ESP whose ITAAC have not yet been satisfied (*i.e.*, the amended EP ITAAC would not be applicable to a combined license where the Commission has made the § 52.103(g) finding with respect to that EP ITAAC). The NRC's consideration of such EP information would be considered to be part of the ESP proceeding, and any necessary changes with respect to EP would therefore be deemed to be changes within the scope of the ESP. The Commission considers this proposal as a means for updating the ESP with respect to EP information in a timely fashion, without imposing undue burden on the ESP holder and the NRC through continuous or periodic updating, while preserving the distinction between the ESP and any referencing combined license proceeding.

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

ESP Updating in Advance of Combined License Application Submission

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

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alternatives, if it decides that updating of environmental and/or EP matters should be accomplished in an ESP proceeding, as opposed to the combined license proceeding in which the ESP is referenced.

Expanding the Scope of Resolved Issues After ESP Issuance

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

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

If the Commission were to allow an ESP holder/combined license applicant to expand the scope of resolved issues in the ESP update proceeding, the Commission believes that the 18-month time period for filing the updating application in the ESP proceeding may be insufficient, and is considering adopting in the final rule a 24-month (2-year) period for filing the ESP updating application, where the ESP holder/combined license applicant seeks to expand the scope of resolved issues. The Commission seeks public comment on whether, in such cases, the Commission should require in the final rule an 18- or 24-month period, or some other period, for submitting its ESP updating application.

Approval in ESP of Process and Criteria for Updating ESP After Issuance

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

While NRC approval of updating procedures and criteria would be reflected in the ESP, the Commission does not believe that the ESP itself must contain the procedures and criteria in order to be accorded finality under § 52.39. An ESP holder/combined license applicant need not comply with any or all of the updating process and criteria, and would be free to use (and justify) other procedures or criteria in the ESP updating proceeding. Naturally, there would be no finality associated with such departures from the ESP-approved procedures and criteria.

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

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

Public Participation in ESP Updating Process

The Commission is considering two ways for allowing public participation in the updating process, if the updating alternative is adopted in the final rule. One approach would be to allow interested persons to challenge the proposed updating by submitting a petition, analogous to that in proposed § 52.39(c)(2), which would be processed in accordance with § 2.206. This approach would be most consistent with the existing provisions in § 52.39, inasmuch as updating of an ESP is roughly equivalent to a request that the terms and conditions of an ESP be modified. A consequence of this approach is that the potential scope of matters which may be raised is not limited to those ESP matters which the ESP holder/combined license applicant and the NRC conclude must be updated.

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

Commenters' Response: Several commenters believed an ESP holder should not be required to update the

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information in the ESP application. These commenters stated that the proposal to require updating would add an unnecessary additional level of review (and possibly hearings) with little or no additional benefit (*i.e.*, the COL applicant would still be under the obligation to update the information provided by the ESP holder). Some commenters contended that an updating requirement would only serve to erode the finality and certainty provided by the ESP, thereby defeating one of the purposes of an ESP. These commenters also believed that an updated requirement would run counter to NRC regulations. Some commenters stated that while the ESP is in effect, the NRC cannot change or impose new requirements, including emergency planning requirements, unless it determines that a modification is necessary either to bring the permit or the site into compliance with the NRC's regulations and orders applicable and in effect at the time the permit was issued, or to assure adequate protection of the public health and safety or the common defense and security. Some commenters argued that the proposed 18-month updating requirement may not be feasible. A commenter gave the following example, "under the NRC's current schedule for the existing ESP applications for North Anna and Grand Gulf, the ESPs will not be issued until 2007, shortly before the planned COL applications for those sites. This would result in insufficient time for the updating envisioned by the NRC, and it would be unfair to those applicants to require them to delay their COL applications to accommodate the updating process. Additionally, the proposed updating process would be inconsistent with § 52.27(c), which permits a COL application to reference an ESP application."

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

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

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

Question 10: The Commission is considering adopting in the final part 52 rulemaking a new provision in § 50.71 that would require combined license holders to update the PRA [probabilistic risk assessment] submitted with the combined license application periodically throughout the life of the facility on a schedule similar to the schedule for final safety analysis report (FSAR) updates (i.e., at least every 24 months) or, alternatively, on a schedule to coincide with every other refueling outage. Updates would be required to ensure that the information included in the PRA contains the latest information developed. The PRA update submittal would be required to contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submittal of the original PRA, or as appropriate, the last update to the PRA under this section. The submittal would be required to include the effects of all changes made in the facility or procedures as reflected in the PRA; all safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) or, in the case of a license that references a certified design, in accordance with § 52.98(c); and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The Commission requests stakeholder feedback on whether such a requirement should be added to the Commission's regulations and, if so, what is an appropriate update schedule.

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

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

Some commenters expressed confusion over the NRC proposal to require PRA updates to reflect safety analyses and evaluations performed by the licensee, and analyses of new safety issues performed by or on behalf of the licensee at the NRC's request. These commenters stated that new analyses

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and evaluations were often performed using design-basis assumptions that may not be appropriate for a PRA. These commenters suggested that only new analyses that impact the PRA warrant consideration, and requested guidance and examples be developed regarding the information that should be considered when updating the plant-specific PRA.

NRC Response: As discussed in further detail in Section V.D.6.b of this document, the Commission is adopting requirements to require maintenance of a PRA, and periodic upgrades every 4 years, by a COL holder beginning at the time of initial operation. These PRAs and upgrades are not required to be submitted to the NRC, but instead should be maintained by the licensee for NRC inspection.

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

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

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

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

b. NEI recommended modification of the Tier 2 definition in Section II.E to clarify that bracketed information in the investment protection short-term availability controls is not part of Tier 2 and thus not subject to the Section VIII.B change controls. The Commission stated in the section-by-section analysis for the AP1000 DCR (71 FR 4464) that some generic technical specifications and investment protection short-term availability controls contain values in brackets. The values in brackets are neither part of the DCR nor are they binding. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic technical specifications or investment protection short-term availability controls. The Commission believes that including this guidance in each DCR is not necessary. The Commission requests comment on whether there are countervailing considerations that favor inclusion of this provision in the DCRs.

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

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

e. NEI recommended modification of the requirement in Section X.A.1 to require the design certification applicant to include all generic changes to the generic technical specifications and other operational requirements in the generic DCD. The Commission believes that inclusion of changes to the generic technical specifications and other operational requirements will enhance the generic DCD and facilitate its use by referencing applicants. The Commission is considering amending each of the DCRs to include the generic technical specifications and other operational requirements in the generic

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DCD and requests public comment on this approach.

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

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

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

i. NEI recommended modification of Section IV.A.2 to clarify the use of "same information" and "generic DCD" in that requirement. The Commission has proposed amending Section IV.A.2 of each DCR to use the phrase "same type of information" to avoid confusion, and requests public comment on this approach.

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

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

l. NEI recommended modification of the requirement in Section VIII.C.4 to include a requirement that operational requirements that were not completely reviewed and approved by the NRC should not be subject to any Tier 2 change controls, e.g., exemptions. However, NEI previously proposed that requested departures from Chapter 16 by an applicant for a COL require an exemption (62 FR 25808; May 12, 1997). The Commission believes that the requirement for an exemption applies to technical specifications and operational requirements that were completely reviewed and approved in the design certification rulemaking (see 62 FR 25825). The Commission requests comment on whether departures from technical specifications and operational requirements that were not completely reviewed and approved should also require an exemption.

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

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

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

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

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

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

Regarding NEI recommendation (f), several commenters supported the use of the term "include" rather than "physically include" for requirements in Section IV of the design certification rules concerning content of COLAs. These commenters also requested clarification on the permissible method of incorporating the generic DCD into the plant-specific DCD portion of the COL application's final safety analysis report (FSAR), because the current NRC position has apparently "led to considerable confusion" among COL preparers. These commenters noted that in the statements of consideration accompanying the AP1000 final rule, NEI recommended a change to the Definitions (Section III.B of that rule, 71 FR 4466). These commenters stated the NRC staff disagreed with this

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recommendation, saying that "the generic DCD should also be part of the FSAR, not just incorporated by reference, in order to facilitate the NRC staff's review of any departures or exemptions." Some commenters believed that this NRC position was in conflict with the former § 52.79(b), which states that the COL application's FSAR "may incorporate by reference the final safety analysis report for a certified standard design," and with § 50.32, which provides for incorporation by reference to eliminate repetitive information. Some commenters argued that although the wording had been altered, the ability to incorporate by reference was preserved in proposed §§ 52.79 (b) and (c), respectively. These commenters claimed this interpretation of incorporation was validated by NRC staff during the Draft Regulatory Guide (DG)–1145 workshops. These commenters stated support for this interpretation and requested the NRC explicitly describe that either approach is acceptable.

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

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

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

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

NRC Response: In response to Question 11.a, the NRC has decided that modification of the generic technical specification definition in Section II.B of the DCRs is not necessary. As stated in the section-by-section analysis for the AP1000 DCR (71 FR 4475; January 27, 2006):

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

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

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

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

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

Regarding Question 11.e, the NRC agrees with NEI's recommendation and has decided to modify the requirement in Section X.A.1 of the DCRs. The Commission believes that the inclusion of changes to the generic technical specifications and other operational requirements in the generic design control document (DCD) will enhance the DCD and facilitate its use by referencing applicants.

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

Several commenters also requested clarification on the permissible method of incorporating the generic DCD in the plant-specific DCD portion of the COL application's final safety analysis report (FSAR), because the NRC position has apparently "led to considerable confusion" among COL preparers. The NRC is requiring COL applicants that reference the DCRs in appendices A through D of part 52 to include the generic DCD in the application's FSAR, in order to facilitate the NRC staff's review of any departures or exemptions. Simply incorporating the generic DCD by reference into the FSAR is not

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sufficient because of the manner in which these existing DCDs were submitted to the NRC. Therefore, Section IV.A.2 of the DCRs overrides §§ 50.32 and 52.79(d). The NRC is hopeful that future DCRs will not have to use this special requirement.

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

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

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

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

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

Regarding Question 11.l, the NRC does not agree with NEI's recommendation to modify Section VIII.C.4 of the DCRs. The requirement in Section VIII.C.4 for an applicant to request an exemption applies to generic technical specifications and operational requirements that were comprehensively reviewed and finalized in the design certification rulemaking (see 62 FR 25825; May 12, 1997). Because this guidance is already set forth in the section-by-section discussion for the DCRs, the NRC has decided that changes to the rule language are not necessary.

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

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

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

Regarding Question 11.p, the NRC agrees with NEI's recommendation to clarify references to the DCDs in Sections X.B.1 and X.B.3 of the DCRs. The references to plant-specific and generic DCD were revised in Sections X.B.1 and X.B.3 to ensure that the requirements in these sections will be properly implemented by applicants and licensees that reference the design certification rules.

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

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

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

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

Several commenters also stated it was "wrong" to require completion of ITAAC in a set time period prior to fuel loading and operation. These commenters indicated that a COL holder would likely complete several ITAAC within 30 days of fuel loading and argued that the NRC should not abrogate responsibility by imposing a mandatory delay on licensees. Some commenters stated the importance of the NRC providing the appropriate level of inspections and reviews to prevent delays in fuel load and emphasized the high cost (stated to be on the order of $1,000,000 per day) of such delay. Some commenters suggested the NRC should be in a position to make a § 52.103(g) finding promptly following the completion of the last ITAAC.

NRC Response: The NRC has decided to amend § 52.99 to require licensees to submit their schedules for completing the inspections, tests, or analyses in the ITAAC. The NRC has added a new paragraph (a) in § 52.99 that requires a licensee to submit to the NRC, no later than 1 year after issuance of the combined license or at the start of construction as defined in 10 CFR 50.10, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. Licensees are required to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, licensees must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under § 52.99(c)(1). Although commenters did not believe that a requirement for submission of a schedule was necessary, the NRC believes it is necessary to ensure that the NRC has sufficient information to plan all of the activities necessary for the NRC to support the Commission's determination as to whether all of the ITAAC have been met prior to initial operation. In the event that licensees consider their schedule information to be proprietary, they can request that the schedule be withheld from public disclosure under § 2.390. If an applicant claims that its construction schedule information submitted to the NRC is proprietary, and requests the NRC to withhold that information under the Freedom of Information Act (FOIA), the NRC will consider that request under the existing rules governing FOIA disclosure in 10 CFR 2.309(a)(4).

The NRC has also decided to amend § 52.99(c) which requires the licensee to notify the NRC that the prescribed inspections, tests, and analyses in the ITAAC have been or will be completed and that the acceptance criteria have been met. The NRC is revising § 52.99(c)(1) in the final rule to more closely follow the language of Section 185b. of the AEA and to clarify that the notification must contain sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met. The NRC is adding this clarification to ensure that combined license applicants and holders are aware that (1) it is the licensee's burden to demonstrate compliance with the ITAAC and (2) the NRC expects the notification of ITAAC completion to contain more information than just a simple statement that the licensee believes the ITAAC has been completed and the acceptance criteria met. The NRC expects the notification to be sufficiently complete and detailed for a reasonable person to understand the bases for the licensee's representation that the inspections, tests, and analyses have been successfully completed and the acceptance criteria have been met. The term "sufficient information" requires, at a minimum, a summary description of the bases for the licensee's conclusion that the inspections, tests, or analyses have been performed and that the prescribed acceptance criteria have been met. The NRC plans to prepare regulatory guidance, in consultation with interested stakeholders, to explain how the functional requirement to provide "sufficient information" with regard to ITAAC submittals could be met.

The NRC is also revising § 52.99(c) by adding a new paragraph (c)(2) requiring that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee shall notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation (consistent with the Section 185.b requirement that the Commission, "prior to operation," find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel. It is the licensee's burden to demonstrate that it will comply with the ITAAC and it must provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met. The term "sufficient information" requires, at a minimum, a summary description of the bases for the licensee's conclusion that the inspections, tests, or analyses will be performed and that the prescribed acceptance criteria will be met. In addition, "sufficient information" includes, but is not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met.

Paragraph (e) has been revised to require that the NRC make available to

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the public the notifications to be submitted under § 52.99(c)(1) and (c)(2), no later than the **Federal Register** notice of intended operation and opportunity for hearing on ITAAC under § 52.103(a). A conforming change is included in § 2.105(b)(3) to require that the § 52.103(a) notice reference the public availability of the § 52.99(c)(1) and (2) notifications. The NRC is requiring that the paragraph (c)(2) notification be made 225 days before the date scheduled for initial loading of fuel, in order to ensure that the licensee notifications are publicly available through the NRC document room and online through the NRC Web site at the same time that the § 52.103(a) notice is published in the **Federal Register**. The NRC's goal is to publish that notice 210 days before the date scheduled for fuel loading, but in all cases the § 52.103(a) notice would be published no later than 180 days before the scheduled fuel load, as required by Section 189.a(1)(B) of the AEA.

Commenters did not support addition of a requirement on completion of ITAAC in a set time period prior to fuel load and the NRC has not included a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date. Instead, the NRC has decided to modify the concept slightly by requiring the licensee to submit, with respect to ITAAC which have not yet been completed 225 days before the scheduled date for initial loading of fuel, additional information addressing whether those inspections, tests, and analyses will be successfully completed and the acceptance criteria met before initial operation. In the case where the licensee has not completed all ITAAC by 225 days prior to its scheduled fuel load date, the NRC expects the information that the licensee submits related to uncompleted ITAAC to be sufficiently detailed such that the NRC can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. In addition, the NRC is adopting the requirements in paragraphs (c)(1) and (c)(2) to ensure that interested persons will have sufficient information to address the Atomic Energy Act, Section 189.a(1), threshold for requesting a hearing with respect to both completed and as-yet uncompleted ITAAC. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes "sufficient information" that must be submitted under paragraphs (c)(1) and (c)(2) demonstrating that the inspections, tests, or analyses for ITAAC have been or will be completed and the acceptance criteria for the ITAAC have been or will be met. The NRC expects that any contentions submitted by prospective parties regarding uncompleted ITAAC would focus on any inadequacies of the specific procedures and analytical methods described by the licensee under paragraph (c)(2), in the context of the findings called for by § 52.103(b)(2).[3]

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

Question 13: ML Hearings. As discussed in Section IV.F.6 of the March 13, 2006, proposed rule, the Commission proposes, as a matter of policy and discretion, that the Commission hold a "mandatory" hearing (*i.e.*, a hearing which, under NRC requirements in 10 CFR part 2, is held regardless of whether the NRC receives any hearing requests or petitions to intervene) in connection with the initial issuance of every manufacturing license. The Commission believes that Section 189.a.(1)(A) of the AEA does not require that a hearing be held in connection with the initial issuance of a manufacturing license. Nonetheless, there are several reasons for the Commission to require by rule, as a matter of discretion, a mandatory hearing. A manufacturing license may be viewed as analogous to a construction permit—a regulatory approval for which Section 189 of the AEA specifically requires that a hearing be held. Even though the Commission's regulations did not address the hearing requirements for manufacturing licenses, the Commission noticed a "mandatory" hearing in connection with the only manufacturing license application ever received by the Agency. *Offshore Power Systems* (Floating Nuclear Power Plants), 38 FR 34008 (December 10, 1973). Accordingly, proposed §§ 2.104 and 52.163 require that a mandatory hearing be held in each proceeding for initial issuance of a manufacturing license. However, the Commission recognizes that there may be countervailing considerations weighing against Commission adoption of a rulemaking provision mandating that a hearing be held in connection with the initial issuance of every manufacturing license where there has been no stakeholder interest in a hearing. If there is no stakeholder interest in a hearing, transparency and public confidence would not appear to be relevant considerations in favor of holding a mandatory hearing. Considerations of regulatory efficiency and effectiveness would be paramount, and would weigh against holding of a mandatory hearing. The Commission requests comments on whether the Commission should exercise its discretion to provide by rule an opportunity for hearing, rather than a mandatory hearing, and the reasons in favor of providing an opportunity for hearing as opposed to holding a mandatory hearing. Based upon the public comments, the Commission may adopt a final rule which deletes § 2.104(f), revises § 2.105 (governing the content of a **Federal Register** notice of proposed action where a mandatory hearing is not held under § 2.104) to add, as appropriate, references to issuance of manufacturing licenses, and revised § 52.163 to provide an opportunity for hearing rather than a mandatory hearing in connection with the initial issuance of a manufacturing license.

Commenters' Response: Several commenters stated there was no need to require mandatory hearings for manufacturing licenses, or that the need for such hearings was unclear. These commenters expressed the belief that such hearings were not an appropriate method for reviewing and resolving

[3] Inasmuch as the ITAAC themselves have already been approved by the NRC and their adequacy may not be challenged except under the provisions of § 52.103(f), a contention which alleges the deficiency of the ITAAC is not admissible under § 52.103(b).

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technical issues. Some commenters advised that the decision to request a hearing be left to either the NRC staff or stakeholders.

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

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

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

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

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

Commenters' Response: Some commenters stated that revisions to NRC regulations should include the current 10 CFR 52.63, which they believed should allow the original design certification applicant (or its successor) to obtain amendments to the design certification rule. These commenters believed current regulations prevented any amendment to a design once the design has been certified by rule (10 CFR 52.63(a)(1)). Some commenters stated that the design certification applicant should be able to petition the NRC for, and obtain, an amendment to the design certification rule to incorporate "beneficial" changes to the design certification, including: (1) Design changes that would result in significant improvements in safety; (2) design changes that would result in significant improvements in efficiency, reliability and/or economics; (3) design changes that result from continuing engineering or design work or are required because of lack of availability of components specified in the original design certification; and (4) design changes necessary to correct minor errors in the original design certification. Some commenters also suggested that where proposed changes involved changes to Tier 2, the design certification applicant should be able to make such changes using a § 50.59-like change process. One commenter noted that changes to allow an amendment to the final design certification could potentially simplify COL applications, reduce NRC staff resource burden, and help assure standardization across the industry.

NRC Response: The NRC has decided to include an amendment process in the final rule that: (1) Reduces unnecessary regulatory burden and maintains protection to public health and safety and common defense and security; (2) provides the detailed design information necessary to resolve selected design acceptance criteria; (3) corrects material errors in the certification information; (4) substantially increases overall safety, reliability, or security of a facility and the costs of the change are justified; or (5) contributes to increased standardization of the certification information, without meeting the special backfit requirement in § 52.63(a)(1)(ii). These amendments will apply to all plants that have referenced or will reference the DCR. The NRC believes that these amendments will enhance standardization by further completing or correcting the certification information. A detailed discussion of the amendment process is provided in Section V.C.7.g of the Supplementary Information of this document.

Question 15: In Section IV.J of the **SUPPLEMENTARY INFORMATION** of the March 13, 2006, proposed rule, the NRC

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outlines key principles regarding its proposal for reporting requirements that implement Section 206 of the Energy Reorganization Act, as amended, for part 52 licenses, certifications, and approvals. The NRC discusses that the beginning of the "regulatory life" of a referenced license, standard design approval, or standard design certification under part 52 occurs when an application for a license, design approval, or design certification is docketed. The NRC also cautions, however, that this does not mean that an applicant is without Section 206 responsibilities for pre-application activities because there are two aspects to the reporting requirements, namely, a "backward looking" or retrospective aspect with respect to existing information, and a "forward looking" or prospective aspect with respect to future information. For an early site permit applicant, the retrospective obligation is that the early site permit holder and its contractors, upon issuance of the early site permit, must report all known defects or failures to comply in "basic components," as defined in part 21. Under the proposed part 21 requirements presented in the proposed rule, the early site permit holder and its contractors are required to meet these requirements upon issuance of the early site permit. Accordingly, applicants should procure and control safety-related design and analysis or consulting services in a manner sufficient to allow the early site permit holder and its contractors to comply with the above described reporting requirements of Section 206, as implemented by part 21. A similar argument applies to design certification applicants. Although the Commission has not proposed an explicit requirement imposing part 21 on applicants for an early site permit or design certification in the proposed rule, it is considering adopting such a requirement in the final part 52 rulemaking because, as a practical matter, the NRC has to require these applicants to implement a part 21 program before approval of the early site permit or design certification. Therefore, providing explicit part 21 requirements for applicants would clarify the Commission's intent. The Commission requests stakeholder comment on whether it should, in the final rule, impose part 21 reporting requirements on applicants for early site permits and design certifications.

Commenters' Response: Several commenters were opposed to the proposed changes to part 21. Some commenters stated part 21 had been in existence for almost 30 years, during which it was never applied to applicants. They complained that they were not aware, and the NRC had not made them aware, of problems that would warrant a change. The commenters noted that applicants take measures to ensure that they were made aware of any errors and deficiencies identified by contractors and suppliers for work performed on commercial nuclear projects, because applicants eventually become holders, and licensees and want equipment to operate correctly. Several commenters were also concerned that the proposal was contrary to the Energy Reorganization Act (ERA), which was the basis for part 21. They believed it would be inappropriate and contrary to the ERA to apply part 21 to applicants. They stated part 21 was established to implement § 206 of the ERA, which applies to "licensees" and vendors, suppliers, and contractors of licensees, not to "applicants." These commenters cited 10 CFR 21.2, stating that the existing regulations of part 21 apply only to entities licensed to possess, use, or transfer radioactive material within the United States, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or fuel storage facility. The commenter believed applicants did not fall within the scope of § 206 of the ERA, and it was inconsistent with the Act to expand the scope of § 21.2 to include applicants.

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

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

NRC Response: The Commission proposed part 21 reporting requirements on applicants for early site permits, design certifications, and standard design approvals in the proposed rule. A detailed discussion on the Commission's rationale for imposing these requirements in the final rule is provided in Section V.J of the **SUPPLEMENTARY INFORMATION** of this document.

V. Discussion of Substantive Changes and Responses to Significant Comments

A. Introduction

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

B. Testing Requirements for Advanced Reactors

This rule amends §§ 50.43, 52.47, 52.79, and 52.157 to achieve clarity and consistency in the testing requirements for advanced reactor designs and plants. This amendment requires applicants for a combined license, operating license, or manufacturing license that use new safety features but do not reference a certified advanced reactor design to also perform the design qualification testing required of certain applicants for design certification. If a combined license application references a certified design, the necessary qualification testing will have been performed under § 52.47(c)(2). The codification of testing requirements in the original § 52.47 was a principal issue during the development of 10 CFR part 52 (see Section II of 54 FR 15372; April 18, 1989). The requirement to demonstrate the performance of new safety features for nuclear power plants that differ significantly from evolutionary light-water reactors or that use simplified, inherent, passive, or other innovative means to accomplish their safety functions (advanced reactors), were included in 10 CFR part 52 to ensure that these new safety features will perform as predicted in the applicant's safety analysis report, to provide sufficient data to validate analytical codes, and that the effects of systems

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interactions are acceptable. The design qualification testing requirements may be met with either separate effects or integral system tests; prototype tests; or a combination of tests, analyses, and operating experience. These requirements implement the Commission's policy on proof-of-performance testing for all advanced reactors and its goal of resolving all safety issues before authorizing construction.

Some commenters stated that it is unnecessary to apply qualification testing requirements to combined license applicants. The Commission does not agree because, when it reformed the licensing process for new nuclear plants with the issuance of part 52, the Commission required applicants to demonstrate that new safety features will perform as predicted in the final safety analysis report. Although the focus of the NRC at that time was on applications for design certification, the Commission intended that testing to qualify new design features (proof-of-performance testing) would be required for all advanced reactors, including custom designs (see Question 6 at 51 FR 24 646; July 8, 1986). Furthermore, it would make no sense for the Commission to require qualification testing for design certification applicants (so-called paper designs) and not require testing for applications to build and operate an advanced nuclear power plant. Therefore, the NRC has implemented its intent in adopting part 52 to resolve issues early and its policy on advanced reactors that it is necessary to demonstrate the performance of new or innovative safety features through design qualification testing for all advanced nuclear reactor designs or plants (including nuclear reactors manufactured under a manufacturing license).

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

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

C. Changes to 10 CFR Part 52

1. Use of Terms: Site Characteristics, Site Parameters, Design Characteristics, and Design Parameters in §§ 52.1, 52.17, 52.U0 , 52.39, 52.47, 52.54, 52.79, 52.93, 52.157, 52.158, 52.167, 52.171, and Appendices A, B, and C to Part 52

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

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

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

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

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reasons, the NRC believes it is important to make the changes described above in order to clarify these terms and their use in part 52 licensing processes.

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

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

3. NRC Staff Information Requests

Section 52.47(a)(3) of the 1989 part 52 rulemaking provided that the NRC staff would advise the design certification applicant on whether there was any additional information beyond that required to be submitted by that section, that must be submitted. The March 2006 proposed rule included analogous provisions (§§ 52.17(d), 52.79(a)(42), 52.137(a)(27), and 52.157(p)) for each of the other licensing and regulatory approval processes in part 52. Upon further consideration in response to a comment on the March 2006 proposed rule, the Commission has decided that these provisions are redundant to § 2.102(a), which provides the NRC staff with overall authority to request information to support their review of an application. Accordingly, §§ 52.17(d), 52.79(a)(42), 52.137(a)(27), and 52.157(p) of the proposed rule have not been adopted in the final rule, and § 52.47(a)(3) is removed from part 52.

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

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

a. Change to a Design Certification

A *change to a design certification* is a generic change to the design certification information which is approved by the Commission in a standard design certification rule under subpart B of part 52. In the four design certifications currently approved by the Commission, the design certification information which is approved by the Commission is either "certified information" and is designated as "Tier 1," or is "approved" and is designated as "Tier 2." The term "generic," means that if the Commission makes a change to the design certification, § 52.63(a) requires that the change ("modification" under § 52.63(a)(3)) be applied to each plant referencing the design certification rule.

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

(1) Requested by the original design certification applicant in accordance with 10 CFR 2.811 (see 10 CFR 2.800(c)), or by any other member of the public, in a petition for rulemaking under 10 CFR 2.802;

(2) Applies to all past nuclear power reactors (including manufactured reactors) whose applications have referenced the design certification, as well as future reactors referencing the design certification rule; and

(3) Requires the Commission provide an exemption to the applicant, if the proposed change is inconsistent with the one or more of the Commission's regulations.

b. Departure

A *departure* as a plant-specific "deviation" from design information in either a standard design certification or a manufacturing license. For a design certification, a departure is a deviation from the certification information which is certified by the Commission in a standard design certification rule (for the current four design certification rules in appendices A through D of part 52, the certification information is "Tier 1" information). For a manufacturing license, a departure is a deviation from any design information approved in the manufacturing license, including technical specifications, site parameters and design characteristics, and interface requirements.[4] A departure may be distinguished from a change to a standard design certification rule (*i.e.*, a change to Tier 1 or Tier 2 information in a design certification rule) or a change to the design approved in a manufacturing license by recalling that a departure is plant-specific. Therefore, a departure:

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

c. Variance

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

(1) Concerns information addressed in an early site permit;

(2) Is requested by the applicant referencing an early site permit;

(3) Applies only to the construction permit or combined license referencing the early site permit; and

(4) Requires the applicant to also obtain an exemption from the Commission's regulations if the proposed variance is inconsistent with one or more of the Commission's regulations.

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

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d. Exemption

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

5. General Provisions

a. Section 52.0, Scope; Applicability of 10 CFR Chapter I Provisions

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

Paragraph (a) of § 52.0 is derived from the text of former § 52.1, but is revised to include standard design approvals and manufacturing licenses within the scope of part 52, and to remove references to Section 104.b of Atomic Energy Act of 1954 (AEA), thereby providing that licenses issued under part 52 are licenses issued under Section 103 of the AEA. After passage of the 1970 amendments to the AEA, all licenses for commercial nuclear power plants with construction permits issued after the date of the amendments were required to be issued as Section 103 licenses. The NRC interprets the 1970 amendment as requiring combined licenses under Section 185 to be issued as Section 103 licenses.[5] Accordingly, the NRC is revising the scope of part 52 to limit its applicability to licenses issued under Section 103 of the AEA.

Paragraph (b) of § 52.0 is a new provision that makes clear that the regulations in 10 CFR Chapter I apply to a holder of, or applicant for an approval, certification, permit, or license issued under part 52 and that any license, approval, certification, or permit, issued under 10 CFR part 52 must comply with these regulations. The need for this paragraph was determined as a result of the July 3, 2003 (68 FR 40026) proposed rule on part 52. In that proposed rule, the Commission proposed a new § 52.5 listing all of the licensing provisions in 10 CFR part 50 that also apply to all of the licensing processes in 10 CFR part 52. This proposal responded to a letter dated November 13, 2001, from the Nuclear Energy Institute (NEI), which stated:

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

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

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

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

Accordingly, in the March 2006 proposed rule, the Commission proposed a different approach, viz., making conforming changes to all of the regulations in 10 CFR Chapter I to specify their applicability to the relevant part 52 regulatory processes, and to add proposed § 52.0(b) to make clear that the regulations in 10 CFR Chapter I apply to the relevant part 52 regulatory processes, and holders and applicants under part 52. The Commission did not receive any comments calling into question the legality of this approach, or otherwise questioning the clarity of the proposed regulatory language. Accordingly, the Commission is adopting this approach in the final part 52, including § 52.0(b).

As discussed elsewhere in this document, the NRC is retaining appendix N in part 52, and revising this appendix to apply to part 52 combined licenses. The provisions of appendix N to part 52 concern applicants for combined licenses under part 52. Therefore, the applicability language in § 52.0, by referring to "licenses" under part 52, need not specifically refer to appendix N to part 52.

b. Section 52.1, Definitions

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

A definition of *modular design* is added to explain the type of modular reactor design which is the subject of the second sentence of § 52.103(g). That provision is added to part 52 to facilitate the licensing of nuclear plants, such as the Modular High Temperature Gas-Cooled Reactor (MHTGR) and Power Reactor Innovative Small Module

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(PRISM) designs, consisting of three or four nuclear reactors in a single power block with a shared power conversion system. During the period that the power block is under construction, the NRC could separately authorize operation for each nuclear reactor when each reactor and all of its necessary support systems were completed. In view of the several definitions of "modular reactor" which are used within the nuclear industry, the Commission intends to avoid future disputes regarding the intended applicability of § 52.103(g) by defining the term, *modular design,* for purposes of part 52.

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

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

c. Section 52.2, Interpretations; and § 52.4, Deliberate Misconduct

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

d. Section 52.3, Written Communications; § 52.5, Employee Protection; § 52.6, Completeness and Accuracy of Information; § 52.7, Specific Exemptions; § 52.8, Combining Licenses; § 52.9, Jurisdictional Limits; and § 52.10, Attacks and Destructive Acts

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

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

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

Section 52.7, which is essentially identical with current § 50.12, is added to address the procedure and criteria for obtaining an exemption from the requirements of part 52. Although part 50 contains a provision (§ 50.12) for obtaining specific exemptions, § 50.12 by its terms applies only to exemptions from part 50. Although it would be possible to revise § 50.12 so that its provisions apply to exemptions from part 52, this is inconsistent with the general regulatory structure of 10 CFR, wherein each part is treated as a separate and independent regulatory unit. The NRC notes that the exemption provisions in § 52.7 are generally applicable to part 52, and do not supercede or otherwise diminish more specific exemption provisions that are in part 52.

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

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

Paragraph (b) of § 52.8, which is analogous to § 50.32, is added to make clear that an applicant for a license, standard design certification, or design approval under part 52 may incorporate by reference in its application information contained in other documents provided to the Commission,

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but must clearly specify the information to be incorporated. This provision was also not included in the March 2006 proposed rule, inasmuch as the NRC determined the desirability of including in part 52 a provision analogous to § 50.32 only after the publication of the March 2006 proposed rule.

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

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

Section 52.10 is added because there is no specific provision in part 52 specifying that the Commission's longstanding determination with respect to the lack of need for design features and other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by United States defense activities, applies to part 52 applicants. The Commission's determination, which was upheld by the U.S. Court of Appeals for the D.C. Circuit, *see Siegel* v. *Atomic Energy Commission*, 400 F.2d 778 (D.C. Cir 1968), is currently codified for part 50 applicants in § 50.13. Although it would be possible to revise § 50.13 so that its provisions apply to applications under part 52, this would be inconsistent with the overall regulatory pattern of 10 CFR Chapter I, whereby each part is treated as a separate and independent regulatory unit. Moreover, any changes to § 50.13 might erroneously be viewed as changes to the Commission's substantive determination on this matter. For these reasons, the Commission is adding new § 52.10 to part 52, which is essentially identical with § 50.13. Inclusion of this provision in part 52 makes clear that applications for combined licenses, manufacturing licenses, design certification rulemakings, standard design approvals, and amendments to these licenses, rulemakings, and approvals under part 52 need not provide design features or other measures for protection of nuclear power plants against attacks by enemies of the United States, or the use of weapons deployed by U.S. 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 U.S. defense activities. The Commission is simply making it clear that its longstanding determination applies to applications under part 52 just as it applies to applications under part 50.

6. Subpart A, Early Site Permits

a. Emergency Preparedness Requirements for Early Site Permit Applicants

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

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

The NRC is adding new § 52.17(b)(3) to require that any complete and integrated emergency plans submitted for review in an early site permit application must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and would operate in conformity with the license, the provisions of the AEA, and the NRC's regulations. The NRC is making these amendments for consistency with the requirements in subpart C of part 52 regarding the review of emergency plans and to provide additional finality to ESP holders. The NRC believes that its review of complete and integrated plans included in an early site permit application should be no different than its review of emergency plans submitted in a combined license application, given that the NRC must make the same findings in both cases, namely, that the plans submitted by the applicant provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC will

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not be able to make the required finding without the inclusion of proposed ITAAC in an early site permit application that includes complete and integrated emergency plans. In the final rule, the NRC has added an allowance that major features of an emergency plan submitted under paragraph (b)(2)(i) of § 52.17 may include proposed ITAAC. This will give an applicant that has proposed major features additional opportunities to achieve finality on major features in cases where ITAAC can be included to address implementation aspects of the major feature.

b. Section 52.13, Relationship to Other Subparts

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

c. Section 52.16, Contents of Applications; General Information and § 52.17, Contents of Applications; Technical Information

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

The title of § 52.17 is revised to read, "Contents of applications; technical information." In response to several comments on the proposed rule, the NRC is including a general grandfathering provision in § 52.17(a) that states, "For applications submitted before September 27, 2007, the rule provisions in effect at the date of docketing apply unless otherwise requested by the applicant in writing." This revision reflects the Commission's belief that ESPs currently under review or issued prior to the effective date of the final part 52 rule should not be required to be modified by this rule. Section 52.17(a)(1) is amended to state that the early site permit application must specify the range of facilities for which the applicant is requesting site approval (*e.g.*, one, two, or three pressurized-water reactors). This new language provides a clearer and more complete statement of the applicant's proposal with respect to the facilities which may be located under the early site permit. This facilitates NRC review, as well as providing adequate notice to potentially-affected members of the public and State and local governmental entities. The NRC assumes that an applicant for an early site permit may not know what type of nuclear plant may be built at the site. Therefore, the application must specify the postulated design parameters for the range of reactor types, the numbers of reactors, etc., to increase the likelihood that approval of the site will resolve issues with respect to the actual plant or plants that the combined license or construction permit applicant decides to build. In a letter dated November 13, 2001 (comment 27 on draft proposed rule text), NEI stated, "The proposed change is too limited. To address the required assessment of major SSCs [structures, systems, and components] that bear on radiological consequences and all items 52.17.a.1.i–vii (sic.), industry recommends new § 52.17a.2." The NRC disagrees with NEI's proposal to have a separate provision for applicants who have not determined the type of plant that they plan to build at the proposed site. The NRC expects that some applicants for an early site permit may not have decided on a particular type of nuclear power plant, therefore, § 52.17(a)(1) was revised to address this situation.

The NRC is amending § 52.17(a)(1) to eliminate all references to § 50.34. The references to § 50.34(a)(12) and (b)(10) are removed because these provisions require compliance with the earthquake engineering criteria in appendix S to part 50 and are not requirements for the content of an application. The reference to § 50.34(b)(6)(v), which requires plans for coping with emergencies, is also being removed. All requirements related to emergency planning for early site permits are addressed in § 52.17(b) and other plans for coping with emergencies will be addressed in a combined license application. Finally, the reference to the radiological consequence evaluation factors identified in § 50.34(a)(1) is being removed and the requirements are included in § 52.17(a)(1). The NRC is modifying the existing requirement for early site permit applications to describe the seismic, meteorological, hydrologic, and geologic characteristics of the proposed site to add that these descriptions must reflect appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated. This addition is to ensure that future plants built at the site would be in compliance with general design criterion 2 from appendix A to part 50 which requires that structures, systems, and components important to safety be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions. The design bases for these structures, systems, and components are required to reflect appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and time in which the historical data have been accumulated.

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

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

The NRC is not requiring applicants to evaluate their site against the applicable sections of Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants." However, the NRC believes that the applicable portions of RG 1.206 can provide useful guidance to ESP applicants in preparing their

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applications and that use of this guidance will facilitate the NRC's review.

The NRC is making a change to § 52.17(a)(1) based on several comments on the proposed rule. The NRC is deleting the requirement in proposed § 52.17(a)(1)(x) that required ESP applicants to address impacts on operating units of constructing new units on existing sites, as well as include a description of the managerial and administrative controls to be used to assure that the limiting conditions of operation for existing units will not be exceeded. The NRC is deleting this requirement because it was contrary to the industry-NRC understanding documented in correspondence in 2003 regarding ESP Topic ESP–19 [see NEI letter dated May 14, 2003 (ML031920U0 6), and NRC letter dated August 11, 2003 (ML031490478)] and because the COL applicant is in the best position to provide such information, since it will have final information regarding the facility design and construction plans. The NRC may include a condition in early site permits that would require the permit holder to notify the operating plant licensee prior to conducting any activities authorized under § 52.25. These controls should be sufficient to evaluate construction activities at a site with an existing operating unit. The NRC has deleted this provision from subpart A in the final rule. COL applicants will, however, continue to be required to meet this provision under § 52.79(a)(31).

The NRC is moving the environmental provisions in former § 52.17(a)(2) to § 51.50(b). Revised § 52.17(a)(2) simply states that an early site permit application must contain a complete environmental report as required by 10 CFR 51.50(b). A discussion of the final rule provisions related to the NRC's environmental review at the ESP stage can be found in the Supplementary Information section that discusses changes to 10 CFR part 51.

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

The NRC is amending § 52.17(c) to clarify that if the applicant wants to request authorization to perform limited work activities at the site after receipt of the early site permit, the application must contain an identification and description of the specific activities that the applicant seeks authorization to perform. This request by the early site permit applicant would be separate from, but not in addition to, a request to perform activities under 10 CFR 50.10(e)(1). The submittal of this descriptive information will enable the NRC staff to perform its review of the request, consistent with past practice, to determine if the requested activities are acceptable under § 50.10(e)(1). If an applicant for a construction permit or combined license references an early site permit with authorization to perform limited work activities at the site and subsequently decides to request authorization to perform activities beyond those authorized under § 52.U0 (c), those additional activities will have to be requested separately under § 50.10(e)(1). Some minor changes were made to the rule language in § 52.17(c) in the final rule to remove references to information being included in either the site safety analysis report or the environmental report. The NRC concluded that it is preferable to include both the list of proposed activities and the redress plan as a separate document in the application, outside of both the site safety analysis report and the environmental report. The NRC's conclusion is based on the fact that the requirements in § 50.10(e) address both safety and environmental issues. Additional changes were made to §§ 51.50, 52.79(a), and 52.80 to implement this concept.

d. Section 52.24, Issuance of Early Site Permit

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

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

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

e. Section 52.27, Duration of Permit

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

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

The NRC is also making revisions to § 52.27 based on public comments. The NRC is deleting proposed § 52.27(b)(2) because it was inconsistent with proposed § 52.39(d) and the NRC's intention that the early site permit be subsumed into the construction permit or combined license once the construction permit or combined license is issued. To make this intention clear, the NRC is also adding new § 52.27(d) in the final rule. This provision states that upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license. By "subsumed" the NRC means that the information that was contained in the early site permit site safety analysis report (SSAR) becomes part of the referencing combined license final safety analysis report upon issuance of the combined license in the same manner as if the combined license applicant had not referenced an early site permit. The NRC is including the phrase "to the extent referenced," to indicate that it is not all of the information submitted in the early site permit application that is subsumed into the combined license, but, only that information that is contained in the SSAR and identified by the applicant as being referenced in the combined license application. This subsumption of the early site permit into the referencing license affects the way changes to the early site permit information will be handled because it breaks the tie to the finality provisions in § 52.39. After issuance of the construction permit or combined license, § 52.39 no longer applies to the early site permit information and such information will be covered by the same finality provisions as the rest of the information in the FSAR (with the exception of any referenced design certification information), as outlined in § 52.98 (*e.g.*, in accordance with §§ 50.54, 50.59, etc.).

f. Section 52.28, Transfer of Early Site Permit

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

g. Section 52.33, Duration of Renewal

Section 52.33 has been revised in the final rule to clarify that the renewal period for an early site permit includes any remaining years on the early site permit then in effect before renewal. This change was made to be consistent with the NRC's regulations concerning renewal of nuclear power plant operating licenses as specified in § 54.31 of this chapter.

h. Section 52.37, Reporting of Defects and Noncompliance; Revocation, Suspension, Modification of Permits for Cause

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

i. Section 52.39, Finality of Early Site Permit Determinations

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

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

(2) Questions regarding whether the early site permit should be modified, suspended, or revoked; or

(3) Significant new emergency preparedness or environmental information not considered on the early site permit.

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

The NRC also regards new emergency preparedness information submitted in the referencing application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness as an issue material to the

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proceeding and appropriate for consideration as a contention in the referencing application proceeding (assuming that all relevant Commission requirements in 10 CFR part 2, such as standing and admissibility, are met). This is a change to the standard that was provided in the proposed rule for new emergency preparedness information and is based on public comments. The proposed rule standard for litigation of emergency preparedness matters was "new or additional information * * * which materially affects the Commission's earlier determination on emergency preparedness, or is needed to correct inaccuracies in the emergency preparedness information approved in the early site permit." Because the final rule language suggested by the commenters is the definition that the NRC gave for information that could "materially affect" the Commission's earlier decision, as indicated in the **SUPPLEMENTARY INFORMATION** section of the 2006 proposed rule, the NRC believes it appropriate to use this language in the final rule itself. The NRC has decided to drop the language that referred to information "needed to correct inaccuracies" because the language, by itself, could have allowed litigation of issues not significant to safety. The NRC believes that the final rule language encompasses all significant emergency preparedness matters that should be subject to litigation.

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

Because new emergency planning or environmental information, if any, will be identified only at the time a license application referencing the early site permit is submitted to the NRC, the NRC believes it is appropriate to address these issues in the proceeding on the referencing application. Other questions regarding whether the permit should be modified, suspended, or revoked will be challenges to the validity of the early site permit. These challenges may be framed in many different ways, e.g., a Commission error at the time of issuance; or actual changes to the site have occurred since issuance of the permit that render some aspect of the permit irrelevant or inadequate to protect public health and safety or common defense and security. The Commission's process for challenges to the validity of a license is contained in 10 CFR 2.206. Accordingly, the Commission concludes that challenges to the validity of an early site permit should be processed in accordance with § 2.206. In the Commission's view, a variance is not fundamentally a challenge to the validity of the early site permit, because it requests dispensation from compliance with some aspect of the permit whose validity remains undisputed. Therefore, the Commission concludes that variances should be treated as proceeding-specific issues of compliance that are potentially valid subjects of a contention in a proceeding for a referencing application.

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

The NRC is clarifying what aspects of the early site permit are subject to the change restrictions in § 52.39(a)(1) by substituting the phrase, "terms and conditions" of an early site permit for the former term, "*requirements.*" Under the new language, the NRC may not change or impose new site characteristics, design parameters, or terms and conditions on the early site permit, including emergency planning requirements, unless the special backfitting criteria in § 52.39(a)(1) are satisfied. No substantive change is intended by this clarification; the language would specify more clearly the broad scope of matters in an early site permit which the NRC intended to finalize. The phrase, "site characteristics, or terms, or conditions, including emergency planning requirements," is used consistently throughout § 52.39 and corresponding provisions in the revisions to § 52.79.

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

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

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

Section 52.39(c) replaces the former criteria in §§ 52.39(a)(2)(i) through (iii), governing how the NRC will treat various issues with respect to the early site permit and its referencing in a combined license application. Matters regarding compliance with the early site permit which would be potentially valid subjects of a contention are listed in §§ 52.39(c)(1)(i) through (iii), e.g., whether the reactor proposed to be built under the referencing application fits within the site characteristics and design parameters specified in the early site permit; whether one or more of the terms and conditions of the early site permit have been met; and whether a variance requested by the referencing applicant is unwarranted or should be modified. The NRC notes that all contentions at the early site permit stage, including a contention pertaining to a variance, must meet the requirements for contentions in § 2.309(f). Matters regarding significant new emergency preparedness or environmental information material to the combined license proceeding, which would be potentially valid subjects of contention under the proposed rule, are listed in §§ 52.39(c)(1)(iv) and (v).

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

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

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

7. Subpart B, Standard Design Certifications

a. Section 52.41, Scope of Subpart

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

b. Section 52.43, Relationship to Other Subparts

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

c. Section 52.45, Filing of Applications

This section presents the requirements for filing design certification applications. This section was reformatted for consistency with the other subparts in part 52 and the references to specific paragraphs within §§ 50.4 and 50.30 were replaced with references to subpart H of part 2. A new

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§ 52.45(c) on design certification review fees, was moved from § 52.49.

d. Section 52.46, Contents of Applications; General Information

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

e. Section 52.47, Contents of Applications; Technical Information

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

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

Some commenters recommended that the requirement to address the standard review plan (SRP) be revised to apply to light-water reactors. The NRC agrees with this comment and has revised this requirement [now § 52.47(a)(9)] to be applicable to light-water-cooled nuclear power plants, but notes that much of the SRP review guidance and criteria are general and would also apply to reviews of gas-cooled reactor designs.

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

Some commenters recommended that the requirement in § 52.47(a)(22) to demonstrate how operating experience insights have been incorporated into the plant design be deleted. The NRC disagrees with this comment. The NRC developed this requirement for future plants (see SRM on SECY–90–377) and it was implemented in past design certification applications by addressing NRC's generic letters and bulletins. The NRC agrees that insights from generic letters and bulletins should be incorporated into the latest revision of the standard review plan (SRP). Therefore, for plant designs that are based on or are evolutions of nuclear plants that have operated in the United States, the applicant should use NRC's generic letters and bulletins issued after the most recent revision of the applicable SRP and 6 months before the docket date of the application. If the application is for a nuclear plant design that is not based on or is not an evolution of a nuclear plant that operated in the United States, the applicant should address how insights from any relevant international operating experience has been incorporated into that plant design.

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

A new § 52.47(b) was created to set forth the required technical contents of a design certification application that are not required to be located in the FSAR. In response to public comments on the proposed rule, the NRC has deleted proposed § 52.47(b)(1) which required design certification applicants to submit a design-specific probabilistic risk assessment (PRA). In its place, the NRC has added new § 52.47(a)(27) which requires that design certification applicants submit a description of the design-specific PRA and its results in the FSAR. The NRC agrees with some commenters that applicants should not be required to submit their complete design-specific PRA and that, instead, applicants should only be required to provide a summary description of the PRA and its results in their FSAR with the understanding that the complete PRA (e.g., codes) would be available for NRC inspection at the applicant's offices, if needed. The NRC expects that, generally, the information that it needs to perform its review of the design certification application from a PRA perspective is that information that will be contained in applicants' FSAR Chapter 19.

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

Some commenters recommended that the requirement in proposed § 52.47(b)(3) (now in 10 CFR 51.55) to evaluate severe accident mitigation design alternatives (SAMDAs) be deleted and that the NRC should initiate a rulemaking or policy statement to disposition SAMDA generically. The NRC disagrees with this comment. The

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NRC has required SAMDA evaluations for previous applications in order to achieve greater finality for the design features that are resolved in design certification rulemakings. Further, the initiation of a rulemaking or policy statement for SAMDAs is outside the scope of the part 52 update rulemaking. As for the perspective that SAMDA evaluations need not be performed for current reactor designs because the severe accident risk for such designs is too remote and speculative, the NRC has already addressed this issue in other contexts. The NRC has considered petitions to eliminate the consideration of SAMDAs previously. The NRC position, both then and now is that it is not prepared to reach the conclusion that the risks of all severe accidents are so unlikely as to warrant their elimination from consideration in our NEPA reviews. As the NRC has stated in response to other requests to confine or eliminate such issues from consideration, if new information in the future provides a firm basis for concluding that severe accidents are remote and speculative, then the NRC may revisit the issue.

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

f. Section 52.54, Issuance of Standard Design Certification

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

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

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

g. Section 52.63, Finality of Standard Design Certifications

The final rule revises the finality provisions in § 52.63(a) to provide processes for amending design certification information without meeting the special backfit requirement in § 52.63(a)(1)(ii). The special backfit requirement restricted changes to certification information, thereby ensuring that all plants built under a referenced certified design would be standardized. Section 52.63(a)(1) was also revised to replace "a modification" with "the change," to clarify that the criteria for changes apply to modifications, rescissions, or imposition of new requirements. In addition, § 52.63 was revised to use the phrase "certification information" in order to distinguish the rule language in the DCRs from the design certification information (e.g., Tier 1 and Tier 2 information) that is incorporated by reference in the DCRs.

Section 52.63(a)(1)(iii) was added to provide the NRC with the ability to make generic changes to the design certification rule language that reduce unnecessary regulatory burdens. The former § 52.63(a)(1) stated that the Commission may not modify, rescind, or impose new requirements on the certification unless the change is: (1) Necessary for compliance with Commission regulations applicable and in effect at the time the certification was issued; or (2) necessary to provide adequate protection of the public health and safety or common defense and security. This requirement did not appear to permit changes to the rule language which reduce unnecessary regulatory burdens in circumstances where the change continues to maintain protection to public health and safety and common defense and security. An example of a change which could not be made under the former § 52.63(a)(1) was a change to the rule language 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).

In Section V of the 2006 proposed rule, Question 14, the NRC stated that it was considering adopting an additional provision in § 52.63(a)(1) that would allow amendments of DCRs to incorporate generic resolutions of design acceptance criteria (DAC) or other design information without meeting the special backfit requirement in the former § 52.63(a)(1). By allowing for an amendment to generically resolve DAC, the NRC would achieve resolution of additional design issues, would achieve finality for those issue resolutions, and would avoid repetitive consideration of those design issues in individual combined license proceedings. The final rule includes an amendment process in § 52.63(a)(1)(iv) that allows for generic resolutions of DAC without meeting the special backfit requirement. These amendments will

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apply to all plants that have or will reference the DCR under § 52.63(a)(2). The NRC believes that these amendments will enhance standardization by further completing the certification information. The NRC will review the amendment application to ensure that the design acceptance criteria are met and that the new design information conforms with the applicable regulations.

Some commenters proposed that the amendment process should allow for generic resolutions of errors in the certification information. The NRC is aware that design certification applicants have discovered errors in their design information after the NRC has completed its review and even after the NRC has certified their design. The final rule includes a new provision in § 52.63(a)(1)(v) to correct material errors in the certification information. This provision is only to be used to correct a material error, which is an error that significantly and adversely affects a design function or analysis conclusion described in the design control document (certification information). The NRC wants to correct material errors by amendment so that these errors will not have to be addressed in individual licensing proceedings.

Many commenters encouraged the NRC to adopt an amendment process that would allow for "beneficial" changes to certification information, would apply the amendment to all plants referencing the certified design, and would only allow amendments prior to issuance of the first combined license that referenced the DCR. The NRC agreed with these comments and included paragraph (a)(1)(vi) to allow for amendments of certification information that will substantially increase the overall safety, reliability, or security of facility design, construction, or operation provided that the direct and indirect costs of implementation of the amendment are justified in view of this increased safety, reliability, or security. However, the NRC does not agree with precluding amendments after issuance of the first combined license. If licensees who referenced a DCR want to adopt a proposed amendment in order to achieve enhanced standardization and the beneficial changes that the amendment would bring, then the NRC may amend the DCR and apply the amendment to all plants referencing the DCR.

Also, some commenters requested that the amendment process allow for changes to the certification information for a wide variety of other reasons. These commenters claimed that the need for a design change may be discovered during detailed design work performed after the original design information was approved by the NRC (so-called first-of-a-kind-engineering) or that certain components in the original design may no longer be available for purchase due to the long duration of a DCR. The NRC's deliberations on this proposal considered the Commission's goal for design certification, which is to achieve and maintain the benefits of standardization. The NRC is still determined to maintain standardization, but has decided to allow amendments for other design changes [see paragraph (a)(1)(vii)] provided that the amendment will be applied to all plants that reference the DCR, thereby increasing standardization. In determining whether to codify a proposed amendment, the NRC will give special consideration to comments from applicants or licensees who reference the DCR regarding whether they want to backfit their plants with these additional design changes.

The final rule includes a new § 52.63(a)(2), which sets forth procedures for rulemakings conducted under § 52.63(a)(1). Paragraph (a)(2)(i) requires that for rulemakings under § 52.63(a)(1), except for rulemakings under § 52.63(a)(1)(ii) necessary to provide adequate protection, the NRC will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a license is under consideration.

The final rule also revised the former § 52.63(a)(2) [now § 52.63(a)(3)] to delete the reference to the former § 52.63(a)(4) [now § 52.63(a)(5)]. The reference to the former § 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 the new § 52.63(a)(3) deals with modifications that the NRC may impose on a DCR under §§ 52.63(a)(4) or 52.63(b)(1). No substantive change is intended by this revision, which merely clarifies the intent of the rule.

Finally, the NRC restates its previous decision regarding the ability of any person to request an amendment to a DCR. In Section II.1.h of the 1989 SOC for part 52 (54 FR 15372), the Commission stated that § 52.63(a)(1) places a designer on the same footing as the NRC or any other interested member of the public. Therefore, anyone may submit a petition for rulemaking to the NRC to correct an error or otherwise amend the certification information. All amendments to the certification information must be accomplished through rulemaking, with an opportunity for public comment under § 52.63(a)(2). Once a certified design is amended by rulemaking, the new rule would apply to all applications referencing the DCR as well as all plants referencing the DCR, unless the change has been rendered "technically irrelevant" through other action taken under §§ 52.63(a)(4) or (b)(1). Also, the NRC will decide whether to codify the proposed amendment based on comments from the referencing applicants and licensees. Thus, standardization is maintained by ensuring that any generic change to the certification information is imposed upon all nuclear power plants referencing the DCR. The duration of the amended DCR will be for the same period of time as the original DCR and have the same expiration date.

8. Subpart C, Combined Licenses

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

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

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

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the duration of an early site permit, absent an application referencing the early site permit. As an alternative to updating throughout the duration of an early site permit, NEI proposed that emergency planning information be updated when an application for a license referencing the early site permit is filed; portions of the emergency plans that are unchanged would continue to have finality under 10 CFR 52.39. In a September 3, 1999 letter, the NRC staff identified updating of emergency preparedness information in early site permits as a possible subject for the part 52 rulemaking.

The NRC agrees in part with the Illinois Department of Nuclear Safety. Emergency plans and/or offsite certificates in support of emergency plans, approved as part of an early site permit review, should be updated. However, emergency plans do not need to be kept up-to-date throughout the duration of an early site permit. There is no need to update the emergency plans approved in an early site permit until the time the permit is referenced in a combined license application. At that time, the emergency plans would have to be reviewed to confirm that they are up-to-date and to provide any new information that may materially affect the NRC's earlier determination on emergency preparedness, or correct inaccuracies in the emergency preparedness information approved in the early site permit in support of a reasonable assurance determination, in accordance with § 50.47 and appendix E to part 50. In addition, the NRC agrees with NEI that a "continuous" early site permit update requirement would impose burdens upon the early site permit holder without any commensurate benefit if the early site permit is not subsequently referenced. Accordingly, the Commission has determined that §§ 52.39 and 52.79 should contain an updating requirement to be imposed upon the applicant referencing an early site permit.

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

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

b. Resolution of ITAAC

Sections 52.99 and 52.103 are revised to incorporate rule language from the design certification regulations in 10 CFR part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of appendix A to part 52). During the preparation of the design certification rules for the ABWR and System 80+ designs, the NRC staff and nuclear industry representatives agreed on certain requirements for the performance and completion of the inspections, tests, or analyses in ITAAC. In the design certification rulemakings, the NRC codified these ITAAC requirements into Section IX of the regulations. The purpose of the requirement in § 52.99(b) is to clarify that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been met.

Section 52.99(c) requires the licensee to notify the NRC that the prescribed inspections, tests, and analyses in the ITAAC have been or will be completed and that the acceptance criteria have been met. The NRC is revising § 52.99(c)(1) in the final rule to more closely follow the language of Section 185b. of the AEA (in response to a late-filed comment) and to clarify that the notification must contain sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met. The NRC is adding this clarification to ensure that combined license applicants and holders are aware that (1) it is the licensees' burden to demonstrate compliance with the ITAAC and (2) the NRC expects the notification of ITAAC completion to contain more information than just a simple statement that the licensee believes the ITAAC has been completed and the acceptance criteria met. The NRC expects the notification to be sufficiently complete and detailed for a reasonable person to understand the bases for the licensee's representation that the inspections, tests, and analyses have been successfully completed and the acceptance criteria have been met. The term "sufficient information" requires, at a minimum, a summary description of the bases for the licensee's conclusion that the inspections, tests, or analyses have been performed and that the prescribed acceptance criteria have been met. The

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NRC plans to prepare regulatory guidance, in consultation with interested stakeholders, to explain how the functional requirement to provide "sufficient information" with regard to ITAAC submittals could be met.

The NRC is also revising § 52.99(c) in the final rule by adding a new paragraph (c)(2) requiring that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee shall notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation (consistent with the Section 189.a(1)(B) requirement governing a request for hearing on acceptance criteria, and the Section 185.b. requirement that the Commission find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel. It is the licensee's burden to demonstrate that it will comply with the ITAAC and it must provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met. The term "sufficient information" requires, at a minimum, a summary description of the bases for the licensee's conclusion that the inspections, tests, or analyses will be performed and that the prescribed acceptance criteria will be met. In addition, "sufficient information" includes, but is not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met.

Paragraph (e) has been revised to require that the NRC make available to the public the notifications to be submitted under § 52.99(c)(1) and (c)(2), no later than the **Federal Register** notice of intended operation and opportunity for hearing on ITAAC under § 52.103(a). A conforming change is included in § 2.105(b)(3) to require that the § 52.103(a) notice reference the public availability of the § 52.99(c)(1) and (2) notifications. The NRC is requiring that the paragraph (c)(2) notification be made 225 days before the date scheduled for initial loading of fuel, in order to ensure that the licensee notifications are publicly available through the NRC document room and online through the NRC Web site at the same time that the § 52.103(a) notice is published in the **Federal Register**. The NRC's goal is to publish that notice 210 days before the date scheduled for fuel loading, but in all cases the § 52.103(a) notice would be published no later than 180 days before the scheduled fuel load; as required by Section 189.a(1)(B) of the AEA.

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

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

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

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

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

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

The NRC revised § 52.99 in the final rule to delete the requirements in proposed § 52.99(a). Proposed § 52.99(a) required holders of COLs to comply with the provisions of §§ 50.70 and 50.71. Because the language in proposed §§ 50.70 and 50.71 requires COL holders to comply with their provisions, and because of the applicability provisions in § 52.0(b), this duplicate requirement in § 52.99 is unnecessary.

The NRC has added a new paragraph (a) in § 52.99 that requires a licensee to submit to the NRC, no later than 1 year after issuance of the combined license or at the start of construction as defined in 10 CFR 50.10, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. Licensees are required to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, licensees must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under § 52.99(c). In Section V of the Supplementary Information of the 2006 proposed rule, the NRC requested stakeholder feedback on whether such a provision should be added to the final rule. Although some commenters did not believe that a regulatory requirement for submission of a schedule was necessary, the NRC believes it is necessary to ensure the NRC has sufficient information to plan all of the activities necessary for the NRC to support the Commission's finding whether all of the ITAAC have been met prior to the licensee's scheduled date for fuel load.

c. Section 52.73, Relationship to Other Subparts

Section 52.73 clarifies that a design approval issued under subpart E of part 52 or a manufacturing license under subpart F of part 52 may also be referenced in an application for a combined license filed under 10 CFR part 52. The former § 52.73 only stated that a combined license may reference a standard design certification or an early site permit. The final rule incorporates into new § 52.73(b) the requirement in the current § 52.63(c) in order to clarify that this requirement applies to applicants for a combined license. This provision requires that, before granting a combined license which references a standard design certification, information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the NRC to make its safety determinations, including the determination that the application is consistent with the certified design. No substantive change is intended by the restatement of this requirement. In a letter dated April 3, 2001 (comments 3 and 3.a), NEI agreed with the proposed change but recommended that the last sentence of § 52.63(c) be deleted and the remaining provision be added to the former § 52.79 rather than the former § 52.73. The NRC agrees with NEI that 10 CFR part 52 should be modified to clarify that the requirement in former § 52.63(c) applied to applicants for a combined license, and that the last sentence be deleted. However, the Commission is adding the remaining provision to the original § 52.73(b), and not to § 52.79, as recommended by NEI.

d. Section 52.75, Filing of Applications

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

e. Section 52.78, Content of Applications; Training and Qualification of Nuclear Power Plant Personnel

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

f. Section 52.79, Contents of Applications; Technical Information in Final Safety Analysis Report; and § 52.80, Contents of Application; Additional Technical Information

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

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

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the NRC has attempted to capture all relevant requirements regarding contents of the FSAR for a combined license application.

In addition, § 52.79(a) contains requirements for descriptions of operational programs that need to be included in the FSAR to allow a reasonable assurance finding of acceptability. This amendment is in support of the Commission's direction to the staff in SRM–SECY–02–0067 dated September 11, 2002, "Inspections, Tests, Analyses, and Acceptance Criteria for Operational Programs (Programmatic ITAAC)," that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application. In this SRM, the Commission stated:

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

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

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

Accordingly, the NRC is adding requirements for descriptions of operational programs. In doing so, the NRC has taken into account NEI's proposal to address SRM–SECY–04–0032 in its letter dated August 31, 2005 (ML052510037). That proposal was reflected in SECY–05–0197 (October 28, 2005, ML052770225), Attachment 1, and approved by the Commission in SRM–SECY–05–0197 dated February 22, 2006 (ML060530316). During the preparation of the final rule, the NRC discovered that several of the operational programs listed in SECY–05–0197 were not addressed in proposed § 52.79. To ensure the list of requirements for the contents of applications is complete, the NRC is adding several new provisions to address operational programs in the final rule. Specifically, the NRC is adding requirements to § 52.79 for COL applicants to include a description of: (1) The process and effluent monitoring and sampling program required by appendix I to 10 CFR part 50 [§ 52.79(a)(16)(ii)]; (2) a training and qualification plan in accordance with the criteria set forth in appendix B to 10 CFR part 73 [§ 52.79(a)(36)(ii)]; (3) a description of the radiation protection program required by § 20.1101 [§ 52.79(a)(39)]; (4) a description of the fire protection program required by § 50.48 [§ 52.79(a)(40)]; and (5) a description of the fitness-for-duty program required by 10 CFR part 26 [§ 52.79(a)(44)]. During the preparation of the final rule, the NRC also noticed that the proposed rule had not completely implemented the Commission's direction regarding the treatment of operational programs in a COL application inasmuch as requirements to address operational program implementation were not included in proposed § 52.79(a). Therefore, in the final rule, the NRC has added requirements to address the implementation of all operational programs required to be described in a COL application. This is consistent with the Commission's position in SRM–SECY–02–0067 that a combined license applicant is not required to have ITAAC for operational programs if the applicant "fully describes the operational program *and its implementation*" in the combined license application [emphasis added].

In addition, the NRC added a new provision to § 52.79(a) in the final rule to address the application requirements in current § 20.1406. Section 20.1406 requires applicants for a license to describe in their application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. To ensure that § 52.79 contains a complete list of the requirements for the contents of a COL application, the NRC added paragraph (a)(45) to § 52.79 to require COL applications to include the information required by § 20.1406. This is not a new requirement but merely a pointer to an existing requirement to include this information.

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

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

The NRC has moved the requirements contained in proposed § 52.79(a)(23) that addressed a request to conduct activities under § 50.10(e) and added them in a new § 52.80(c). The NRC concluded that it is preferable to include both the list of proposed § 50.10(e) activities and the redress plan as separate documents in the application, outside of both the site safety analysis report and the environmental report. The NRC's conclusion is based on the fact that the requirements in § 50.10(e) address both safety and environmental issues. Additional changes were made to §§ 51.50 and 52.17 to implement this concept.

Some commenters recommended that the requirement in § 52.79(a)(37) to demonstrate how operating experience insights have been incorporated into the plant design be deleted. The NRC disagrees with this comment. The NRC developed this requirement for future plants (see SRM on SECY–90–377) and it was implemented in past design certification applications by addressing NRC's generic letters and bulletins. The NRC agrees that insights from generic letters and bulletins should be incorporated into the latest revision of the standard review plan (SRP). Therefore, for plant designs that are

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based on or are evolutions of nuclear plants that have operated in the United States, the applicant should use NRC's generic letters and bulletins issued after the most recent revision of the applicable SRP and 6 months before the docket date of the application. If the application is for a nuclear plant design that is not based on or is not an evolution of a nuclear plant that operated in the United States, the applicant should address how insights from any relevant international operating experience has been incorporated into that plant.

Section 52.79(a)(41) requires that the applicant evaluate the facility against the standard review plan (SRP). For COL applicants that reference the same design certification rule and adopt a design-centered approach in preparing their COL applications, the NRC expects that the "reference application" will fully conform with this requirement and then any follow-on applications will not need to provide the evaluations for the application information that is identical to the reference application. The NRC did not require applicants to evaluate their facility against RG 1.206, "Combined License Applications for Nuclear Power Plants." However, the NRC believes that RG 1.206 can provide useful guidance to COL applicants in preparing their applications and that use of this guidance will facilitate the NRC's review.

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

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

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

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

Section 52.79(d) describes the requirements for combined license applications that reference a standard

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

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

Section 52.80 is added to cover the required technical contents of a combined license application that are not contained in the FSAR. These application contents include the ITAAC, the environmental report, and the request to perform activities under § 50.10(e) with the associated redress plan. This last item was moved to § 52.80(c) in the final rule from its location in § 52.79(a)(23) in the proposed rule. The NRC concluded that it is preferable to include both the list of proposed activities and the redress plan as separate documents in the application, outside of both the site safety analysis report and the environmental report. The NRC's conclusion is based on the fact that the requirements in § 50.10(e) address both safety and environmental issues. Additional changes were made to §§ 51.50 and 52.17 to implement this concept.

g. Section 52.81, Standards for Review of Applications

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

h. Section 52.83, Finality of Referenced NRC Approvals; Partial Initial Decision of Site Suitability

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

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

i. Section 52.89, Environmental Review

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

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j. Section 52.91, Authorization To Conduct Site Activities

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

k. Section 52.93, Exemptions and Variances

Paragraph (a) of § 52.93, which includes a discussion of the requirements regarding requests for an exemption from any part of a referenced design certification, is revised to state that the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced design certification rule, or with § 52.63 if there are no applicable exemption provisions in the referenced design certification rule. This provision formerly referred to compliance with § 50.12(a). The NRC is revising paragraph (b) of this section in the final rule to include an allowance for applicants to request a variance from the early site permit SSAR. The allowance for requesting variances to the SSAR was inadvertently omitted in the proposed rule. Because the majority of the early site permit information that a combined license applicant will be referencing will be the information in the SSAR, it is logical that the allowance to request variances be extended to the information in the SSAR given that the NRC is allowing variances to the permit itself. In the final rule, the NRC is also adding a provision to paragraph (b) of this section that precludes the NRC from issuing a variance once a construction permit, operating license, or combined license referencing the early site permit is issued; any changes that would otherwise require a variance should instead be treated as an amendment to the construction permit or combined license.

Section 52.93 is also revised in the final rule to add a discussion of requests for departures from a referenced nuclear power reactor manufactured under a manufacturing license in new paragraph (c) of this section. This provision was inadvertently omitted in the proposed rule, although similar provisions were addressed in the proposed rule in §§ 52.98 and 52.171. However, the proposed rule incorrectly used the term "variance" to describe an application-specific change to a reactor manufactured under a manufacturing license. The NRC has corrected these provisions in the final rule to use the term "departure" for such changes, consistent with the terminology used for changes to a referenced design certification. New paragraph (c) of this section is consistent with these other sections and states that an applicant for a combined license who has filed an application referencing a nuclear power reactor manufactured under a manufacturing license may include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The NRC may grant a request only if it determines that the departure will comply with the requirements of 10 CFR 52.7, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The criteria for granting the departure is the exemption criterion in § 52.7; however, the departure itself is not considered an exemption (unless, of course, the departure also involves a non-compliance with an underlying Commission regulatory requirement in 10 CFR Chapter I). Thus, the Commission will not approve a departure unless the Commission finds, in addition to the routine exemption criteria in § 52.7, that special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. These limitations are intended to maintain the standardization of manufactured reactors in operation to the extent practicable. The licensee may not depart from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor through the provisions of § 50.59.

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

l. Section 52.97, Issuance of Combined Licenses

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

m. Section 52.98, Finality of Combined Licenses; Information Requests

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

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license, except in accordance with the provisions of §§ 52.103 or 50.109, as applicable.

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

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

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

n. Section 52.103, Operation Under a Combined License

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

o. Section 52.104, Duration of Combined License; § 52.105, Transfer of Combined License; § 52.107, Application for Renewal; § 52.109, Continuation of Combined License; and § 52.110, Termination of License

Five new provisions are added to subpart C of part 52 for consistency with the other subparts in 10 CFR part 52 and to parallel requirements in 10 CFR part 50 for operating licenses. Section 52.104, addresses the duration of a combined license and contains requirements that formerly existed in § 52.83. In addition, the Commission has amended these requirements to indicate that, where the Commission has allowed operation under a combined license during an interim period under § 52.103(c), the period of operation is not to exceed 40 years from the date allowing operation during the interim period.

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

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

9. Subpart D, Reserved

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

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

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discussion on 10 CFR 52.43 in this document).

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

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

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

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

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

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

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

A new § 52.139, which specifies the standards that will be used to review applications for design approvals and new §§ 52.145 and 52.147, which specify the finality and duration of design approvals was added to be consistent with other subparts. In a letter dated November 13, 2001, NEI commented that "Industry recommends FDAs be valid for 15 years." The Commission agrees with NEI's recommendation and has decided that the duration of standard design approvals should correspond to the duration of design certifications, inasmuch as both design approvals and design certifications constitute approvals of nuclear power plant designs, and the period of effectiveness of the approval from a technical standpoint is not a function of whether the approval is granted by the NRC staff or the Commission. Some commenters recommended that § 52.147 be rewritten to provide for renewals of standard design approvals. The Commission disagrees with this comment. The original appendix O to part 52 did not contain a process for renewing design approvals and most of the design approvals issued under appendix O to part 52 were for a 5-year duration. In this rulemaking, the Commission has tripled the duration for a design approval and believes that renewals will not be necessary. Also, as stated before, the Commission favors the use of the design certification process, which includes a process for renewals.

11. Subpart F, Manufacturing Licenses

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

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

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place of manufacture to the site where it is to be operated.

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

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

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

Information which must be submitted as part of an application, but is not typically considered part of a final safety analysis report, is identified in § 52.158. This includes proposed ITAAC to be used by the licensee who will construct and operate a nuclear power plant at its site using the manufactured reactor and an environmental report for the manufactured reactor. Note that, in the final rule, the NRC has moved proposed § 52.158(a) to a new § 52.157(f)(31) which requires that manufacturing license applicants submit a description of the design-specific PRA and its results in the FSAR. The NRC agrees with some commenters that applicants should not be required to submit their complete design-specific PRA and that, instead, applicants should only be required to provide a summary description of the PRA and its results in their FSAR with the understanding that the complete PRA (e.g., codes) would be available for NRC inspection at the applicant's offices, if needed. The NRC expects that, generally, the information that it needs to perform its review of the manufacturing license application from a PRA perspective is that information that will be contained in applicants' FSAR Chapter 19.

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

Section 52.163 of the March 2006 proposed rule would have required that the NRC conduct a "mandatory" hearing in connection with the initial issuance of a manufacturing license, even though the AEA does not require a mandatory hearing for issuance of manufacturing licenses. For the reasons set forth in the NRC's response to Commission Question 2, and the discussion on §§ 2.104 and 2.105, the NRC has decided not to require a "mandatory" hearing for initial issuance of a manufacturing license, and § 52.163 is revised in the final rule to refer to a publication of a notice of proposed action under § 2.105, rather than a notice of hearing under § 2.104.

In light of the NRC's review and approval of a final design as part of issuance of a manufacturing license, the final rule provides a greater degree of finality to a manufacturing license as compared with a standard design certification. Under § 52.171(a)(1), the same degree of issue finality accorded to the "certified design" applies throughout the term of the manufacturing license. Under this

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provision, the NRC may not impose any change or modification to the approved design (including site parameters, or design characteristics) for the manufacturing license unless the NRC determines that the change or modification is necessary either for adequate protection or for compliance with requirements applicable and in effect at the time the manufacturing license was issued. Similarly, the manufacturing license holder may not make changes to the design under the provisions of 10 CFR 50.59. Any change to the design will require a license amendment. The Commission regards this as similar to the level of change control imposed on designs which are the subject of a standard design certification. The Commission is imposing this stringent level of change control because one of the key reasons for licensing manufactured reactors is to enhance standardization—one of the original objectives of the 1989 part 52 rulemaking. Unlike design certification, which is an approval of a "paper design," the NRC's proposed concept of a manufacturing license is pre-approval of the procurement, manufacturing, and quality assurance processes that translates the approved reactor design into a manufactured assembly in a controlled environment, with the capability to optimize techniques and procedures based upon feedback. Some of these advantages may be lost if each "manufactured" reactor were treated as a "one-off" custom product. Imposing the discipline of a license amendment process should ensure that a profusion of changes are not made to the approved design at random intervals. The Commission disagrees with commenters on the proposed rule that the design of a manufactured reactor should be subject to less-stringent change provisions than a standard design certification. The commenters have not demonstrated that there are special or unique aspects of manufacturing, as compared with the construction of a nuclear power plant based upon a referenced standard design certification, that would weigh against maintaining the high degree of design standardization achieved by design certification. One commenter correctly noted that changes in such manufacturing matters as procurement, manufacturing processes, or quality assurance are not subject to the proposed § 52.171(b)(1) change restriction, because these matters do not constitute changes to the approved design of the reactor to be manufactured. These changes would be governed by the applicable change process and restrictions already established in the Commission's regulations such as § 50.59, and § 50.54(a), and may not require license amendments.

The only relevant rationale provided by the commenters is that obsolescence of components and component manufacturers' changes would necessitate minor changes to the reactor design over a 15-year period. Although the Commission acknowledges the likelihood of these factors, the NRC staff does not see any reason why these factors are more likely to affect the design of a manufactured reactor as compared with the design approved in a design certification. It is not clear why a change in component sourcing would necessarily result in a "design change" requiring an amendment to the manufacturing license. Finally, the Commission notes that the proposed rule does not mandate "zero changes in a reactor design." As specifically stated in the SOC of the March 13, 2006 (71 FR 12801), proposed rule (second column), proposed § 52.171(b)(1) would allow the manufacturer to make changes to the approved design to be manufactured, albeit by license amendment.

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

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

Under § 52.177(c), the holder of a manufacturing license may not commence manufacturing of a reactor less than 3 years before the expiration date, but may continue the manufacturing of a reactor whose manufacture commenced before the 3-year deadline up to license expiration. If, however, an application for renewal is timely-filed with the NRC, manufacturing of a reactor whose manufacture commenced before the 3-year deadline may continue until the time that the NRC completes action on the renewal application in accordance with the Timely Renewal Doctrine of the Administrative Procedure Act (APA). The Commission believes that the timely renewal period should be based upon the time reasonably needed by the agency to complete action on a renewal application, so that an applicant's reliance upon timely renewal is the rare exception rather than the rule. The NRC selected the 3-year deadline as a reasonable period for completing the manufacture of a nuclear power reactor, based in large part upon public statements by various reactor vendors that they have set goals for constructing complete nuclear power plants onsite within 3 years. It seems reasonable, therefore, that a manufactured reactor, built in a controlled environment using industrial manufacturing processes, would be able to be manufactured in the same 3-year period as the construction of an entire facility onsite. Paragraph (b) is corrected in the final rule by removing the phrase, "that the Commission may impose," in order to avoid the possible misinterpretation that the Commission could choose not to impose new adequate protection requirements identified by the Commission. In addition, paragraph (b)(2) is corrected by removing the reference to "site permit" and substituting the term, "manufacturing license."

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

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of the duration of a renewed operating license under part 54).

12. Subpart G of Part 52 [Reserved]

13. Subpart H of Part 52—Enforcement

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

14. Appendices A, B, C, and D to Part 52—Design Certifications for ABWR, System 80+, AP600, and AP1000

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

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

In an earlier rulemaking (see 64 FR 53582; October 4, 1999), the NRC revised § 50.59 to incorporate new thresholds for permitting departures from a plant design as described in the FSAR without NRC approval. For consistency and clarity, similar changes were adopted for part 52 applicants or licensees. Because of some differences in how the requirements are structured in the DCRs, certain criteria contained in § 50.59 are not necessary for or applicable to part 52 and are not being included in this rule. One criterion definition that the NRC did include was from § 50.59 for a "Departure from a method of evaluation," which is appropriate to include in this rulemaking so that the eighth criterion in paragraph VIII.B.5.b of appendices A, B, and C to part 52 will be implemented as intended.

Each of the DCRs includes a special process in Section VIII for departures from selected severe accident issues. The Commission believes that the resolution of severe accident issues should be preserved and maintained in the same fashion as all other safety issues that were resolved during the design certification review (refer to SRM on SECY–90–377). However, because of the increased uncertainty in severe accident issue resolutions, the Commission codified separate criteria in paragraph B.5.c of Section VIII for determining if a departure from design information that resolves these severe accident issues would require a license amendment. The final rule amends paragraph B.5.c to clarify that the special process applies to ex-vessel severe accident design features that are described in the plant-specific design control document (DCD).

For purposes of applying the special criteria in paragraph B.5.c of Section VIII, severe accident resolutions are limited to those design features where the intended function of the design feature is relied upon to resolve postulated accidents when the reactor core has melted and exited the reactor vessel (ex-vessel severe accidents) and the containment is challenged. The location of the ex-vessel severe accident design information in the DCD is not important to the application of this special departure process in paragraph B.5.c. Some design features may have intended functions to meet both "design basis" requirements and to resolve ex-vessel severe accidents. If these design features are reviewed under paragraph VIII.B.5, then the appropriate criteria from either paragraph B.5.b or B.5.c are selected depending upon which function the departure is being taken from.

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

The amendment to paragraph X.B.3.b of appendices A, B, and C to part 52 reduced the frequency of reporting during the period of construction and increased the frequency of reporting during the application review period. The NRC believes that these changes in the reporting burden balance each other and provide the information needed by the NRC to fulfill its responsibilities in the licensing of future nuclear power plants. In order to make the finding

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under § 52.103(g), the NRC must monitor the design changes made under Section VIII of the DCRs. 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, the detailed design of the plant before and during construction, and during pre-operational 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 operating plant requirements.

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

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

Prior to this final rulemaking, appendix N in parts 50 and 52 contained the NRC's procedures governing the review and issuance of licenses for nuclear power plants of "duplicate design." Hearings for applications filed under appendix N in both parts 50 and 52 are governed by subpart D of part 2. In the March 2006 proposed rule, the NRC proposed deleting appendix N in part 52, and retaining these provisions only in part 50. Although no comment was received on this proposal, the NRC has decided to withdraw its proposal to delete appendix N in part 52. Since the preparation of the March 2006 proposed rule, several industry groups have announced their intention to seek combined licenses utilizing the same design. In view of this industry development, the NRC believes that there is potential utility to keeping the option of appendix N in part 52 open to potential combined license applicants. Accordingly, the NRC is retaining in part 52 the procedural alternative provided in appendix N to part 52, and to revise its language to make its provisions applicable to combined licenses using identical designs. As part of this revision, the NRC set forth more explicit direction on the information to be submitted, the NRC docketing review, notice, and the content of the EIS under appendix N of part 52. However, the NRC decided against a wholesale revision of appendix N to part 52, together with conforming changes in part 51, inasmuch as these changes were not the subject of public comment, and because such a course of action would have delayed the overall part 52 rulemaking. Inasmuch as the changes to appendix N of part 52 constitute, in essence, revisions to the NRC's rules of procedure and practice (albeit located within part 52), the NRC may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

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

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

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

Paragraph 5 of appendix N to part 52 provides that, upon an NRC determination that each application is acceptable for docketing under 10 CFR 2.101, each application will be separately docketed (i.e., each application will be given a separate docket number, but that docket number may include a special designator signifying that it is part of a group of applications filed under appendix N to part 52). Ordinarily, the NRC will publish in the **Federal Register** a separate notice of docketing for each application, so that delays in the docketing of one application will not delay the docketing and subsequent technical review of other applications filed in accordance with appendix N to part 52. However, if circumstances allow (e.g., sufficiency review for multiple applications are completed simultaneously), the NRC may publish a single notice of docketing for multiple applications. The notice of docketing must state that the application will be processed under the provisions of 10 CFR part 52, appendix N and subpart D of part 2. As discussed under subpart D of part 2, the NRC also has discretion to either publish a notice of hearing for each application (possibly with the period for the filing of petitions to intervene running from the notice of hearing for the last application of the group), or to publish a joint notice of hearing for multiple applications.

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

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

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certification or manufactured reactor. For example, a common design could reference the use of a specific design certification and a common ultimate heat sink. In such circumstances, the ACRS would issue a common report limited to the safety matters for the ultimate heat sink.[6]

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

D. Changes to 10 CFR Part 50

1. General Provisions, § 50.2, Definitions

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

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

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

2. Requirement of License, Exceptions, § 50.10, License Required

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

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

3. Classification and Description of Licenses

a. Section 50.23, Construction Permits

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

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

a. Section 50.30, Filing of Application; Oath or Affirmation

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

b. Section 50.33, Contents of Applications; General Information

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

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

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authority to conduct the activities permitted under § 50.10(e)(1). The NRC has determined that no safety finding *per se* is necessary to authorize the licensee to conduct these activities. The NRC's review of a § 50.10(e)(1) application is focused on siting and environmental matters.

With respect to a standard design approval, the argument applies with even more force, inasmuch as a design approval authorizes no activities of any kind, and the finality associated with a design approval is significantly less than for an early site permit. The NRC concludes that no regulatory purpose appears to be served by a financial qualifications review for early site permits and standard design approvals. The NRC believes that there is little additional regulatory value in requiring a financial qualifications review for a manufacturing license. While it is true that a lack of sufficient financial resources could result in inadequate manufacture of a reactor, under the NRC's proposed concept of a manufacturing license under subpart F of part 52, each manufactured reactor cannot be operated until ITAAC specified in the manufacturing license are successfully completed by the licensee authorized to construct the nuclear power facility using the manufactured reactor. Successful completion of the manufactured reactor's ITAAC should ensure that any problems with manufacture attributable to lack of financial resources of the manufacturing license holder can be identified before operation. Moreover, the licensee authorized to construct the facility (either under a construction permit or a combined license) using a manufactured reactor would have been subject to a financial qualifications review. This review should be sufficient to determine if the applicant has sufficient financial resources to carry out facility construction and the completion of the manufactured reactor's inspections, tests, and acceptance criteria. Finally, the NRC notes that it does not require the fabricators of safety-related and important to safety structures, systems, and components (SSCs) to be licensed and subject to a financial qualifications review. The NRC believes that a holder of a manufacturing license conducts activities which appear to be, in large part, analogous to these current non-licensed fabricators. Accordingly, the NRC concludes that a financial qualifications review of the applicant for a manufacturing license will not add significant regulatory value to justify the cost of such a review.

Section 50.33(g) addresses radiological emergency response plans for State and local government entities that must be submitted in applications for operating licenses. The final rule makes a conforming change to ensure that applicants for combined licenses must also submit this information, as well as applicants for early site permits who decide under § 52.17(b)(2)(ii) to seek NRC review and approval of complete emergency plans. In addition, § 50.33(g) provides requirements for the plume exposure pathway emergency planning zone (EPZ) and the ingestion pathway EPZ. The NRC has made a conforming change to § 50.33(g) in the final rule to address early site permit applications that propose major features of emergency plans describing the EPZs under 10 CFR 52.17(b)(2)(i). Such provisions were inadvertently left out of the proposed rule. For an application for an early site permit that proposes major features of the emergency plans describing the EPZs, the change requires the descriptions of the EPZs, to meet the requirements of § 50.33(g). This is necessary for the NRC to be able to find that major features describing the EPZs are acceptable under § 52.18.

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

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

c. Section 50.34, Contents of Construction Permit and Operating License Applications; Technical Information

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

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

d. Section 50.34a, Design Objectives for Equipment To Control Releases of Radioactive Material in Effluents—Nuclear Power Reactors; and § 50.36a, Technical Specifications on Effluents From Nuclear Power Reactors

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

e. Section 50.36, Technical Specifications

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

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

f. Section 50.36a, Technical Specifications on Effluents From Nuclear Power Reactors

Section 50.36a(a) requires each licensee of a nuclear power reactor to include technical specifications to keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable. The former language in § 50.36a(a) encompassed combined license holders. However, applicants for design certification are also required to include proposed technical specifications on effluents in their applications by virtue of the provision in current § 52.47(a)(1)(i) which states that an application for design certification must contain the technical information which is required of applicants for construction permits and operating licenses by 10 CFR part 50

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which is technically relevant to the design and not site-specific. In addition, former appendix M to 10 CFR part 50, Section M.1, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety to manufacturing licenses. Therefore, Section 50.36a(a) is revised to state that each licensee of a nuclear power reactor and each applicant for a design certification or a manufacturing license will include technical specifications to keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable. The proposed rule did not include the provisions for manufacturing licenses. However, proposed § 52.157(e)(18) did require manufacturing license applicants to include proposed technical specifications in accordance with § 50.36a. Therefore, it was clearly the NRC's intent that the provisions of § 50.36a be applicable to manufacturing license applications and the NRC has corrected this omission in the final rule.

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

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

g. Section 50.36b, Environmental Conditions

Section 50.36b authorizes the Commission to include conditions to protect the environment in each license authorizing operation of a production or utilization facility and each license for a nuclear power reactor facility for which the certification of permanent cessation of operations required under § 50.82(a)(1) has been submitted. These conditions are to be derived from information contained in the environmental report and the supplement to the environmental report as analyzed and evaluated in the NRC record of decision. The conditions must identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

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

h. Section 50.37, Agreement Limiting Access to Classified Information

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

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ensure that access to classified information is adequately controlled by all entities applying for NRC licenses, design certifications, or design approvals.

5. Standards for Licenses, Certifications, and Approvals

a. Section 50.40, Common Standards

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

b. Section 50.43, Additional Standards and Provisions Affecting Class 103 Licenses and Certifications for Commercial Power

The text and heading of this section are revised to clarify that certain additional standards and provisions for class 103 licenses apply to applications for combined licenses, design certifications, and manufacturing licenses issued under part 52, in addition to applications for construction permits and operating licenses issued under part 50. Section 50.43(e) is added to clarify that the requirements to demonstrate new safety features by testing, which were previously set forth in part 52, apply to applicants for operating licenses issued under part 50 and applicants for combined licenses, design certifications, and manufacturing licenses issued under part 52. This amendment conforms to the goal of having reactor safety requirements in part 50 and procedural requirements in part 52. Only the requirements in § 50.43(e) apply to applications for design certification. Refer to the generic discussion on testing requirements for advanced reactors in Section V.B of this document.

c. Section 50.45, Standards for Construction Permits, Operating Licenses, and Combined Licenses

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

d. Section 50.46, Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors

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

e. Section 50.47, Emergency Plans, § 50.54(gg), and Appendix E to Part 50, Emergency Planning and Preparedness for Production and Utilization Facilities

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

The NRC is making some additional changes to § 50.47(a)(1) in the final rule. Proposed § 50.47(a)(1)(ii) stated that "Except as provided in paragraph (e) of this section, no initial combined license under part 52 of this chapter will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency." In the final rule, the NRC is removing the phrase "except as provided in paragraph (e)" because paragraph (e) does not address issuance of the combined license, but, rather, addresses the Commission finding under § 52.103(g). Likewise, the NRC is making a change to paragraph (e) of this section in the final rule to remove the reference to paragraph (a) of this section.

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

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

Section 50.47(d) formerly provided that no NRC or Department of Homeland Security (DHS) review, findings, or determinations concerning the state of offsite emergency preparedness or the adequacy of and capability to implement State and local or utility offsite emergency plans are required before issuance of an operating license authorizing only fuel loading or low-power testing and training (up to 5 percent of the rated power). Section 50.47(d) further stated that a license authorizing fuel loading and/or low-power testing and training may be

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

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

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

In Section IV of appendix E to part 50, the NRC is modifying paragraph F.2.a, to address combined licenses in addition to operating licenses. Paragraph F.2.a currently provides requirements regarding the conduct of full participation exercises and states that a full participation exercise shall be conducted within 2 years before the issuance of the first operating license for full power of the first reactor. Paragraph F.2.a also requires that, if the full participation exercise is conducted more than 1 year before issuance of an operating licensee for full power, an exercise which tests the licensee's onsite emergency plans shall be conducted within 1 year before issuance of an operating license for full power. The NRC is designating the requirements for operating licenses as paragraph F.2.a.i, and adding a new paragraph F.2.a.ii that contains the requirements for combined licenses. Paragraph F.2.a.ii states that, for a combined license, the first full participation exercise must be conducted within 2 years of the scheduled date for initial loading of fuel and operation under § 52.103. Paragraph F.2.a.ii also requires that, if the first full participation exercise is conducted more than 1 year before the scheduled date for initial loading of fuel and operation under § 52.103, an exercise which tests the licensee's onsite emergency plans must be conducted within 1 year before the scheduled date for initial loading of fuel and operation under § 52.103. The modifications further state that, if DHS identifies one or more deficiencies in the state of offsite emergency preparedness as the result of the first full participation exercise, or if the NRC finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) will apply, as previously discussed.

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

The NRC is also modifying Section V of appendix E to part 50, which states

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that no less than 180 days before the scheduled issuance of an operating license for a nuclear power reactor or a license to possess nuclear material, the applicant's detailed implementing procedures for its emergency plan shall be submitted to the Commission. Paragraph V also requires that licensees submit any changes to the emergency plan or procedures to the NRC within 30 days of these changes. The NRC is clarifying that paragraph V is also applicable to COL holders by stating that they must submit their detailed implementing procedures for their emergency plans to the NRC no less than 180 days before the scheduled date for initial loading of fuel. The wording of this requirement has been changed slightly in the final rule. In the proposed rule, this provision required that COL holders submit their detailed implementing procedures for their emergency plans to the NRC no less than 180 days before the date that the Commission authorizes fuel load and operation under § 52.103. The NRC has modified the provision to make the target date 180 days before scheduled date for initial loading of fuel because this will be a known date whereas the licensee would not know the date that the Commission will make the § 52.103(g) finding. This change is also consistent with other requirements in appendix E that are tied to the scheduled date for initial fuel load.

f. Section 50.48, Fire Protection

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

g. Section 50.49, Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants

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

h. Section 50.54, Conditions of Licenses; and § 50.55, Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses

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

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

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

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

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

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

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

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

Section 50.55(c) makes the license conditions in § 50.54 also apply to construction permits, unless otherwise modified. In the proposed rule, the NRC revised this paragraph to add a reference to combined licenses. However, upon further consideration, the NRC has determined that no change to § 50.55(c) is necessary because the introduction to § 50.54 outlines which provision in that section apply to combined licenses.

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

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

i. Section 50.55a, Codes and Standards

Section 50.55a provides requirements relating to codes and standards for construction permits and operating licenses for boiling or pressurized water-cooled nuclear power facilities. The NRC is revising § 50.55a to clarify how the regulations in § 50.55a apply to approvals, certifications, and licenses issued under 10 CFR part 52. Section 50.55a formerly applied to combined licenses by virtue of the provision in current § 52.83, which stated that all provisions of 10 CFR part 50 and its appendices applicable to holders of construction permits and operating licenses also apply to holders of combined licenses. Also, § 50.55a formerly applied to design certifications by virtue of the provision in former § 52.48, which states that design certification applications will be reviewed for compliance with the standards set out in 10 CFR part 50 as it applies to applications for construction permits and operating licenses for nuclear power plants, and as those standards are technically relevant to the design proposed for the facility. Although former appendix O to part 52 does not explicitly require applicants for design approvals to comply with the requirements of § 50.55a, the NRC is requiring design approval holders to comply with § 50.55a because the NRC believes that the requirements for a design approval should be the same as the requirements for design certification, given that the reviews performed by the NRC staff for the two products are essentially identical. Finally, appendix M to part 52, Section M.1, states that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses. Therefore, the NRC is modifying § 50.55a to state that each combined license for a utilization facility is subject to the conditions in § 50.55a, but is only subject to the conditions in §§ 50.55a(f) and (g) after the NRC makes the finding under § 52.103. The modifications to § 50.55a also state that each manufacturing license, design approval, and design certification application is subject to the conditions in §§ 50.55a(a), (b)(1), (b)(4), (c), (d), (e), (f)(3), and (g)(3), which are the provisions related to nuclear power facility design.

j. Section 50.59, Changes, Tests, and Experiments

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

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k. Section 50.61, Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events

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

l. Section 50.62, Requirements for Reduction of Risk From Anticipated Transients Without Scram (ATWS) Events for Light-Water-Cooled Nuclear Power Plants

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

m. Section 50.63, Loss of All Alternating Current Power

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

n. Section 50.65, Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants

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

6. Inspections, Records, Reports, Notifications

a. Section 50.70, Inspections

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

Section 50.70(b)(1) 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 existing language in this provision encompasses combined license holders and manufacturing license holders. Section 50.70(b)(2) provides requirements regarding the space to be provided for a site with a single power reactor facility licensed under 10 CFR part 50 and for sites containing multiple power reactor units. The NRC is revising § 50.70(b)(2) to clarify that these requirements also apply to sites for combined license holders under 10 CFR part 52 and to facilities issued manufacturing licenses under 10 CFR part 52.

b. Section 50.71, Maintenance of Records, Making of Reports

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

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

Section 50.71(e) establishes the updating requirements for the FSAR, including the information that must be included in each update. The former regulation, however was deficient in two respects. First, it did not address the updating requirements for combined license applicants and holders. Second,

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the regulation, if applied to manufacturing licenses under subpart F of part 52, imposed unnecessary regulatory burden with respect to periodic updating.

Accordingly, the NRC is revising § 50.71(e) to specify the FSAR updating requirements for combined license applicants and holders. In addition, current § 50.71(f) is redesignated as § 50.71(g), and a new § 50.71(f) is added.

Section 50.71(e)(3)(iii) is added to contain the provisions applicable to combined license holders during the period of time from docketing of the application to the Commission finding under § 52.103(g). The update frequency during this period is established as annually, which is consistent with requirements in Section X.B.3.b of the design certification rules in appendices A through D of part 52 for combined license holders that reference those rules. After the Commission finding under § 52.103(g), the frequency would be governed by § 50.71(e)(4), as for other operating reactors.

Section 50.71(f) is revised to require the holder of the manufacturing license to update the FSAR to reflect any modifications to the design of the reactor authorized to be manufactured which have been approved by the NRC under § 52.171, or any new analyses requested to be performed by the NRC. Periodic updating of an 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.

Paragraph (g), formerly (f), is being revised to add reference to § 52.110(a)(1) for permanent cessation of operation for plants licensed under part 52.

Finally, paragraph (h) is being added to 50.71. This paragraph contains requirements for licensees to maintain and upgrade the PRA periodically throughout the plant life. These provisions apply only to COLs under part 52, but are included in part 50 in this section covering maintenance of records and making of reports, consistent with the Commission's practice elsewhere in development of the requirements for the part 52 processes.

These new requirements are a culmination of the Commission's interest in use of risk-informed processes as articulated in its 1995 Policy Statement ("Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," (60 FR 42622; August 16, 1995)).In the original part 52 rule, each design certification holder was required to include as part of the application a design-specific PRA. The Commission has been engaged in an effort to improve PRA quality through support and endorsement of consensus standards on PRA methods.

In the proposed rule published in March 2006, the Commission included a specific request for comment (Question 10, "New Requirements for Periodic Updates to the PRA"—see section IV of this document) about part 52 licensees periodically updating the PRA throughout the life of the facility, on a schedule similar to that for FSAR updates. Several commenters noted that the proposed rule did not include a frequency for updating the PRA. These commenters stated that they believed that PRA update frequency should be addressed in guidance rather than regulations. These commenters indicated a frequency of once every two operating cycles would be reasonable and consistent with existing requirements in 10 CFR 50.69(e). After considering the comments received, the Commission has decided to require combined license holders to maintain and upgrade a PRA to meets endorsed standards over the lifetime of the facility. To implement this decision, new requirements are being placed in § 50.71(h).

Paragraph (h)(1) requires each holder of a combined license, by the time of the scheduled fuel load date for the facility, to develop a plant-specific PRA. The PRA is to be both level 1 and level 2 and must cover those modes of operation and initiating events for which NRC-endorsed consensus standards are in effect one year prior to that date. Level 1 refers to the identification and quantification of sequences leading to the onset of core damage. Level 2 refers to identification and quantification of severe accident progression and containment response. Additional information about scope and quality of PRA to meet these provisions will be addressed in the NRC documents endorsing the standards, or in the standards themselves.

The one year time period was chosen to allow time for the licensee to develop and upgrade its PRA and conduct peer review prior to the date when the PRA must be completed (i.e., by the scheduled date for initial fuel load). The scheduled fuel load date was selected because the COL holder chooses this date, and thus is in a position to determine when the "one-year prior" requirement comes into effect. Note that this provision does not require that this PRA be submitted to the NRC for review and approval. The need for any such submittal or review would be determined by any risk-informed application for which the licensee might wish to use this PRA, such as in support of licensing actions.

Paragraph (h)(2) requires the COL holder to maintain the PRA until permanent cessation of operations under § 52.110(a). The Commission intends PRA maintenance to be consistent with how it is defined in the American Society of Mechanical Engineers (ASME) "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications" (ASME–RA–Sb–2005), that is "the update of the PRA models to reflect plant changes, such as modifications, procedure changes or plant performance." No specific frequency is defined in the rule for such maintenance; the Commission expects licensees to follow the ASME (or other consensus body) guidance on this aspect.

The paragraph further provides that the PRA must be upgraded every four years, to cover initiating events and operational modes contained in NRC-endorsed consensus standards in effect one year prior to each required upgrade. The Commission intends PRA upgrade to be consistent with how it is defined in consensus standards, such as ASME–RA–Sb–2005, that is, "the incorporation into a PRA model of a new methodology or significant changes in scope or capability." If no new standards are issued during a four-year upgrade cycle, licensees would not be required to upgrade their PRAs; however, the requirement to maintain the PRA would still be in effect. It should also be noted that there may be situations where a PRA upgrade is needed more frequently than the four year cycle, as for instance to support a new risk-informed application.

Finally, paragraph (h)(3) specifies that each holder of a combined license shall, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA to

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cover all modes and all initiating events. This requirement is not premised on the existence of NRC-approved consensus standards, and an all-mode, all-initiator PRA must be developed even if standards do not yet exist. The requirement to develop and maintain such a PRA by the time of license renewal application is intended only to establish a timing requirement for completing the upgrade of the PRA, and does not have any implications on the current requirements for license renewal. The upgraded PRA is not an element of any (i.e., past, present, or future) review or approval of a license renewal application.

In implementing these new requirements, it is the NRC's expectation that industry stakeholders will work with the NRC and appropriate codes and standard setting bodies to continually upgrade the relevant codes and standards, identify potential issues, resolve problems, and create relevant guidance to assist in periodically improving the quality and comprehensiveness of the PRA.

c. Section 50.72, Immediate Notification Requirements for Operating Nuclear Power Reactors

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

d. Section 50.73, Licensee Event Report System

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

e. Section 50.75, Reporting and Recordkeeping for Decommissioning Planning

The requirements in § 50.75 are intended to ensure that entities who construct and ultimately operate a nuclear power plant will have sufficient funds at the end of the operational life of the plant to complete the decommissioning of the plant. Section 50.75 requires a nuclear power plant operating license application to address the predicted costs of decommissioning, provide financial assurance by one of the means specified in the regulation, and submit evidence that one or more of these means has been established. Section 50.75 also requires the operating license holder to update the cost estimates for decommissioning on an annual basis, and to submit reports to the NRC every 2 years describing, *inter alia*, any adjustments to the amount of funds collected annually to reflect any changes in projected decommissioning cost. When a plant is within 5 years of its projected end of its operation, the reports must be submitted annually, and a site-specific decommissioning cost estimate must be submitted. Some of these requirements are directed at the two phase licensing process in 10 CFR part 50, in which the NRC issues a construction permit followed by an operating license. These requirements are not well-suited to the combined license process under part 52. For example, requiring the combined license applicant to comply with the current requirement in § 50.75(b)(4) that the operating license applicant submit a copy of the financial instrument obtained to satisfy the requirements of § 50.75(e), would place a more stringent requirement on the combined license applicant, inasmuch as that applicant would be required to fund decommissioning assurance at an earlier date as compared with the operating license applicant.

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

The proposed rule would have required the combined license holder to submit, by March 31 of each year until the date that the NRC authorizes fuel load under § 52.103(g), an updated certification of the information required by paragraph (b)(1). The proposed rule also would have required the combined license holder to submit, no later than 30 days after the Commission publishes notice in the **Federal Register** under § 52.103(a), a certification that financial assurance is being provided in the relevant amount together with a copy of the financial instrument obtained to satisfy the requirements of § 50.75(e). Once the Commission has made the finding under § 52.103, the proposed rule would have required the combined license holder to be subject to the reporting and updating requirements as an operating license holder under part 50, including the requirements applicable when the plant is within 5 years of the projected end of operation. A commenter objected to the annual reporting requirement, arguing that an annual update during the construction period would serve no purpose and is unnecessary and unduly burdensome. The commenter proposed that the holder be allowed to adjust or update the original certification at the time construction is complete and the plant is ready to begin operation. Upon

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further consideration, the Commission has decided to modify the final rule by eliminating the requirement for annual reports, and instead requiring the updating reports 2 years and 1 year before the date scheduled for initial loading of fuel load (consistent with the schedule required by § 52.99(a)). The Commission's objective is to have sufficient time to evaluate the projected costs of decommissioning, and any licensee-proposed changes in the financial assurance mechanism for funding before fuel is loaded into the reactor and operation commences. This will allow the Commission to take any necessary regulatory action before fuel loading and commencement of operation.

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

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

7. US/IAEA Safeguards Agreement

a. Section 50.78, Installation Information and Verification

Since 1980, the U.S./International Atomic Energy Agency (IAEA) Safeguards Agreement has allowed IAEA inspection and verification activities at U.S. facilities that the IAEA selects from the U.S. Eligible Facilities List. The safeguards agreement is implemented under the Nuclear Non-Proliferation Treaty, which provides assurance that all nuclear materials declared to be in peaceful use are not diverted to potential use in nuclear explosives. Although 10 CFR part 75 contains most of the NRC requirements intended to implement the installation, inspection, and verification provisions of the Safeguards Agreement with IAEA, § 50.78 requires each holder of a construction permit to submit certain information on Form N–71, permit verification by representatives of the IAEA, and take any other action necessary to implement the Safeguards Agreement. Inasmuch as combined licenses authorize construction of a nuclear power plant at a fixed site, the provisions of § 50.78 should also apply to a holder of a combined license under part 52. Accordingly, § 50.78 is revised to specify that holders of combined licenses must, if requested by the NRC, submit installation information on Form N–71, permit verification of that information by the IAEA, and take other action as may be necessary to implement the Safeguards Agreement, in the manner set forth in § 75.6, and §§ 75.11 through 75.14.

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

a. Section 50.80, Transfer of Licenses

Section 50.80 implements Sections 101 and 184 of the AEA, which require Commission approval for the transfer of a license for a production or utilization facility, including a nuclear power reactor. Section 50.80(a) explicitly refers to transfers of a "license for a production or utilization facility * * *," which would include construction permits under part 50, as well as all licenses and permits issued under part 52. However, to explicitly recognize the applicability of § 50.80(a) to both permits under parts 50 and 52 and all licenses under part 52, § 50.80(a) is revised to explicitly refer to permits under parts 50 and 52, and licenses under part 52. The proposed rule would have only made these clarifying revisions. A commenter on the proposed rule stated that some of the requirements in § 50.80 are not relevant to transfers of an ESP. The NRC agrees, and has revised the final rule to specify which criteria are applicable to transfer of an ESP. Specifically, paragraph (b)(1)(ii) requires an application for transfer of an ESP to include as much of the information described in §§ 52.16 and 52.17 with respect to the identity and technical qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. This change removes the requirement for the applicant for transfer of an ESP to address financial qualifications since this is not required of an initial ESP applicant. In addition, this change removes the provision that the NRC may require additional information as part of an ESP transfer with respect to data on proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards. Information on these subject matters is not relevant to an ESP transfer, inasmuch as an ESP does not authorize the holder to possess radioactive material.

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

b. Section 50.81, Creditor Regulations

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

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9. 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 is making a number of changes in these regulations.

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

Sections 50.92 and 50.91(a)(4) implement the Commission's authority under Section 189 of the AEA to dispense with the advance publication of a **Federal Register** document requesting a hearing with respect to license amendments, and to make operating license and combined license amendments immediately effective upon issuance, if the NRC finds that the amendment involves no significant hazards consideration. The NRC is revising § 50.92(c) to clarify that, consistent with Section 189 of the AEA, the NRC may make a no significant hazards consideration determination for amendments of combined licenses under part 52. Combined licenses are explicitly mentioned in Section 189.a.(2)(A) of the AEA with respect to immediate effectiveness following a Commission determination of a no significant hazards consideration. In addition, a combined license merges into a single license the authority otherwise contained in a construction permit and an operating license, and the language of Section 189.a.(1)(A) of the AEA which refers to both amendments of construction permits and operating licenses, also applies to amendments of combined licenses.

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

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

a. Section 50.100, Revocation, Suspension, Modification of Licenses, Permits, and Approvals for Cause

Section 50.100 is revised to explicitly address the Commission's authority to suspend, modify, or revoke any standard design approval under subpart E of parts 50 or 52 for any material false statement in the application, or because of any statement in any report, record, inspection, or condition revealed by the application, or by other means, which would warrant the NRC to refuse to grant the design approval on an original application. The former language of § 50.100, which is retained as paragraph (a) in the final rule, applied to any license or any license or construction permit issued under part 50 for any material false statement in the application for the license or permit, or because of any statement in any report, record, inspection, or condition revealed by the application, or by other means, which would warrant the NRC to refuse to grant a license on an original application, or for failure to construct or operate a facility in accordance with the applicable license or permit. While this language applies to early site permits, combined licenses and manufacturing licenses, by virtue of their status as licenses under the AEA, it does not clearly apply to standard design approvals as these are not licenses. Nonetheless, the Commission possesses authority to modify, suspend or revoke the regulatory approvals. Accordingly, the NRC is revising this section to add a reference to a standard design approval.

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

11. Backfitting

a. Section 50.109, Backfitting

The backfit rule, 10 CFR 50.109, provides certain protection to nuclear power plant licensees against changes in the NRC requirements and NRC staff positions on those requirements. Prior to the final rule, the backfitting provisions in § 50.109 applied to standard design approvals, construction permits, and operating licenses, but did not address combined licenses or manufacturing licenses. Part 52 contains special backfitting requirements on early site permits, design certification rules, but prior to this rulemaking, neither § 50.109 or part 52 addressed backfitting of a combined license, although the NRC recognizes that backfitting restraints for an early site permit and a design certification rule would apply to a combined license referencing either or both. To address these gaps in backfitting, and to clarify the application of special backfitting provisions, § 50.109(a)(1) is revised by establishing the date that backfitting protection begins for a manufacturing license, a construction permit for a duplicate design license, and a combined license. Moreover, with respect to a part 50 construction permit, a part 50 operating license, and a part 52 combined license, § 50.109 is revised by listing the specific backfitting restrictions that apply if an early site permit, standard design approval, or standard design certification rule is referenced, or if a nuclear power reactor manufactured under a part 52 manufacturing license is used.

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

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12. Enforcement

a. Section 50.120, Training and Qualification of Nuclear Power Plant Personnel

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

13. Appendices

a. Appendix A to Part 50—General Design Criteria for Nuclear Power Plants

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

b. Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

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

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

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

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

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controls to each early site permit activity associated with the generation of design information for safety-related SSCs that meet the criteria in appendix B to part 50. Therefore, the NRC is revising appendix B to part 50 to make it applicable to early site permits.

c. Appendix C to Part 50—A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Construction Permits and Combined Licenses

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

With the exception of manufacturing licenses, none of the other regulatory processes under part 52, e.g., early site permits, standard design certifications, and standard design approvals, authorize any activities constituting "construction" under the AEA and the Commission's regulations.[7] Therefore, the final rule does not refer to early site permits, design certifications, or design approvals under part 52. With respect to a reactor manufacturing license, the NRC does not believe that a financial qualifications review is necessary for several reasons. A financial qualifications review at the manufacturing license stage would appear to be redundant to the financial qualifications review that is already necessary at the construction permit and operating license stages, or combined license stage. Sufficient safety and quality assurance reviews, including the use of ITAAC in the case of a combined license, should be sufficient to address any adverse impacts on safety as the result of inadequate financial resources to properly manufacture the reactor. Furthermore, the NRC notes that manufacture of a reactor is, in many respects, no different than fabrication of components and systems by third party vendors, who are not required to obtain an NRC license and demonstrate financial qualifications. There seems to be no regulatory value to mandate a financial qualifications review of manufacturing license applicants, when this type of review is not conducted by the NRC for fabricators of nuclear power plant systems and components.

d. Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

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

e. Appendix I to Part 50—Numerical Guides for Design Objectives and Limiting Conditions for Operation To Meet the Criterion "as Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents

The Commission is revising appendix I to part 50 to conform to the changes in §§ 50.34a and 50.36a which are being made as part of this final rule. Specifically, a statement is added in Section I of appendix I to part 50, stating that §§ 52.47, 52.79, 52.137, and 52.157 provide that applications for design certification, combined license, design approval, or manufacturing license, respectively, shall include a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems. In addition, Section II of appendix I to part 50 is revised to state that the guides on design objectives set forth in appendix I to part 50 may be used by an applicant for a combined license as guidance in meeting the requirements of § 50.34a(d) or by an applicant for a design approval, a design certification, or a manufacturing license as guidance in meeting the requirements of § 50.34a(e). Section IV of appendix I to part 50 is revised to state that the guides on limiting conditions for operation for light-water-cooled nuclear power reactors in appendix I to part 50 may be used by an applicant for an operating license or a design certification or combined license, or a licensee who has submitted a certification of permanent cessation of operations under § 50.82(a)(1) or § 52.110 as guidance in developing technical specifications under § 50.36a(a) to keep levels of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable. Finally, Section V of appendix I to part 50 is revised to state that the guides for limiting conditions for operation set forth in appendix I are applicable to any application filed on or after January 2, 1971, for a construction permit for a light-water-cooled nuclear power reactor, or a design certification, a combined license, or a manufacturing license for a light-water-cooled nuclear power reactor under part 52. Note that the NRC added the phrase "for a light-water-cooled nuclear power reactor" to Section V in the final rule. This phrase was inadvertently left out of the introduction to Section V in the proposed rule. The NRC did not intend to change the applicability of appendix I in this rulemaking and is, therefore, correcting this omission in the final rule. The NRC has also removed the conforming change it had proposed to paragraph A.3 of the Concluding Statement of Position of the Regulatory Staff (Docket–RM–50–2) Guides on Design Objectives for Light-Water-Cooled Nuclear Power Reactors in appendix I. The design objectives in this staff position are only applicable to those light-water-cooled nuclear power reactors that applied for a construction permit before January 2, 1971 (per Appendix I, Section V, B.2.). Because part 52 did not exist before 1971, the proposed change is unnecessary.

f. Appendix J to Part 50—Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors

Section 50.54(o) provides a condition for all operating licenses for water-cooled power reactors that primary reactor containments must meet the containment leakage test requirements set forth in appendix J to part 50. These test requirements provide for preoperational and periodic verification by test of the leak-tight integrity of the primary reactor containment, and systems and components which penetrate containment of water-cooled power reactors, and establish the acceptance criteria for these tests. The purpose of the tests are to assure that leakage through the primary reactor containment systems and components penetrating primary containment shall not exceed allowable leakage rate values

[7] 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."

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as specified in the technical specifications or associated bases, and periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment. The Commission is revising appendix J to clarify that these requirements also apply to combined licenses under 10 CFR part 52. This is consistent with former § 52.83, which stated that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses.

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

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

h. Appendix S to Part 50—Earthquake Engineering Criteria for Nuclear Power Plants

Appendix S to part 50 provides earthquake engineering criteria for nuclear power plants and applies to applicants for a design certification or combined license under part 52 or a construction permit or operating license under part 50. The final rule revises appendix S to clarify that the requirements in appendix S also apply to applicants for design approvals and manufacturing licenses issued under 10 CFR part 52. Although former appendix O to part 52 did not explicitly require applicants for design approvals to comply with the requirements of appendix S, the NRC is requiring design approval holders to comply with appendix S to part 50 because the NRC believes that the requirements for a design approval should be the same as the requirements for a design certification, given that the reviews performed by the NRC staff for the two products are essentially identical. Finally, appendix S formerly applied to manufacturing licenses by virtue of former appendix M to part 52, Section M.1, which stated that the provisions in part 50 applicable to construction permits apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to manufacturing licenses. Therefore, the Commission is revising the General Information section of appendix S to part 50 to state that the appendix applies to applicants for a design certification, design approval, combined license, or manufacturing license under 10 CFR part 52 or a construction permit or operating license under 10 CFR part 50. The NRC also made conforming changes to the Introduction, paragraph (a) to appendix S to part 50, and added definitions for *design approval* and *manufacturing license* to Section III of appendix S to part 50, to be consistent with the definitions in proposed part 52.

E. Change to 10 CFR Part 1

1. Section 1.43, Office of Nuclear Reactor Regulation

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

F. Changes to 10 CFR Part 2

1. Section 2.1, Scope

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

2. Section 2.4, Definitions

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

3. Section 2.100, Scope of Subpart

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

4. Section 2.101, Filing of Application

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

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

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contain the information required by §§ 50.34(a) and 50.34a if the application is for a construction permit, or § 52.79 and § 52.80(a) if the application is for a combined license. In addition, the part that is filed first must contain the information required by § 50.33, § 50.34(a)(1) if the application is for a construction permit, § 52.79(a)(1) if the application is for a combined license, and § 50.37. There are no considerations unique to combined licenses which would weigh against allowing a combined license applicant to submit a two part application under paragraph (a)(5) of § 2.101. Accordingly, the Commission is adopting this change in the final rulemaking. Inasmuch as the revisions are to the Commission's rules of procedure and practice, the Commission may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

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

5. Section 2.102, Administrative Review of Application

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

6. Section 2.104, Notice of Hearing

Section 2.104 sets forth the NRC's requirements regarding publication in the **Federal Register** of notice of hearings. The former rule, as well as the proposed part 52 rule, specified the nature of the issues that the presiding officer must address in both uncontested and contested proceedings. The NRC has decided, based upon its experience in noticing hearings in the last decade (in which the Commission's notices for more significant proceedings have varied from requirements in this section), as well as its consideration of the nature of mandatory hearings under Section 189 of the AEA, that much of this detailed prescription of the content of the notice of hearing should be removed from § 2.104.

Accordingly, the language of § 2.104 has been considerably truncated from the former rule. Paragraph (a) is largely the same as former paragraph (a). However, paragraph (b) has been modified to specify only the requirements of the notice of hearing which are common to all proceedings. All provisions in the former § 2.104 specifying the issues to be addressed by the presiding officer are removed in the final rule. Inasmuch as this revision is to the NRC's rules of procedure and practice, the NRC may adopt them in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

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

7. Section 2.105, Notice of Proposed Action

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

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

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

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included in the **Federal Register** notice of intended operation.

8. Section 2.106, Notice of Issuance

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

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

9. Section 2.109, Effect of Timely Renewal Application

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

10. Section 2.110, Filing and Administrative Action on Submittals for Standard Design Approval or Early Review of Site Suitability Issues

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

11. Section 2.111, Prohibition of Sex Discrimination

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

12. Section 2.202, Orders

This section is revised by redesignating § 2.202(e) as § 2.202(e)(1), and adding §§ 2.202(e)(2) through (5), to indicate the backfitting provisions in part 52 applicable to the various licensing processes under part 52. No provisions were deemed necessary to address issuance of orders representing backfitting of NRC approvals such as standard design approvals.

13. Section 2.309, Hearing Requests, Petitions To Intervene, Requirements for Standing, and Contentions

Section 2.309, which establishes the NRC requirements governing requests for hearing and petitions to intervene—including submission of contentions—is revised to add three conforming and clarifying changes. First, paragraph (a) is revised, consistent with a change to § 52.103(c), to make clear that in a proceeding under § 52.103, the Commission itself will act as the presiding officer, will consider and act upon a request for a hearing under § 52.103, and will also determine whether a period of interim operation may be permitted, as provided for under Section 189.a(1)(B)(iii) of the AEA. Inasmuch as the Commission itself will make the contention admission determination, there should be no need for further Commission review of the contention admission decision at the end of the hearing.

Second, paragraph (f)(1)(i) has been revised to make clear that contentions in § 52.103(b) requests for hearing must raise issues in law or fact with respect to whether one or more of the acceptance criteria in a combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection to public health and safety. This is consistent with the statutory limitation on the scope of a hearing in Section 189.a(1)(B)(ii) of the AEA.

Third, a new paragraph (f)(1)(vii) has been added to set forth the specific requirements for a contention under Section 189.a(1)(B)(ii) and 10 CFR 52.103(b). The new paragraph provides that, in a request for hearing under § 52.103(b), the information submitted must be sufficient and include supporting information showing, *prima facie*, that: (i) One or more of the acceptance criteria in a combined license have not been, or will not be met, and (ii) the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection to public health and safety. The revision also makes clear that the information in support of a contention that an acceptance criterion is not, or will not be met, must identify the specific portions of the § 52.99(c) report which is inaccurate, incorrect, or incomplete. The terms, "inaccurate," and "incorrect," while somewhat overlapping, are intended to cover a broad range of situations. "Inaccurate" is intended to address a situation where information contained in, referenced by, or relied upon (either explicitly or implicitly) as a supporting basis for a representation in a § 52.99(c) report, is erroneous (*e.g.*, an erroneous computation, or inaccurate data entry of a test result). By contrast, "incorrect" focuses on a situation where such information is the result of a cognitive inadequacy or failure (even if, under the circumstances, the inadequacy or failure is justifiable), poor judgement, negligence, or deliberate wrongdoing. By "incomplete," the NRC means that the report does not provide the information which must be provided in the report as required by § 52.99. Furthermore, if the requestor contends that the § 52.99(c) report is incomplete, and the requestor contends that the incomplete portion prevents the requestor from making the necessary prima facie showing, then the requestor must also, as provided by § 2.309(f)(1)(vii), explain why the deficiency (viz., the incomplete nature of the report) prevents the requestor from making the necessary prima facie

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showing. The NRC believes that these changes to § 2.309 will help ensure that any 10 CFR 52.103 hearing on whether the acceptance criteria in ITAAC have been, or will be met, is focused only on the matters which Congress intended to be adjudicated at this juncture, as directed by Section 189.a.(1)(B) of the AEA.

Fourth, paragraph (g) is revised to conform with the change in: (i) 10 CFR 52.103(c), which now provides that the Commission will act as the presiding officer in determining whether to grant or deny a request for hearing with respect to whether acceptance criteria in ITAAC have been or will be met; and (ii) 10 CFR 2.310, which provides that the Commission, acting as the presiding officer, will determine the hearing procedures to be utilized in a § 52.103 hearing. Under the revised paragraph (g), a request for hearing under § 52.103 shall not address the hearing procedures to be utilized.

Fifth, paragraph (h) is revised to prohibit a reply by a requestor for a hearing under § 52.103. The NRC believes that Congress intended the Commission's initial decision to grant the hearing and the determination of interim operation to be based upon the same set of information. The Commission's view is based upon the language of Section 189.a.(1)(B)(iii), which refers to a Commission determination to allow a period of interim operation based upon the "petitioner's prima facie showing and any answers thereto. * * *" That the statute only refers to a request and the answers thereto suggests that Congress did not intend that a reply was necessary. This is understandable given Congress" explicit direction that any hearing granted be completed "to the maximum possible extent * * * within 180 days of the publication of the notice [of opportunity to request a hearing under Section 189.a(10)(B)(i)] or the anticipated date for initial loading of fuel into the reactor, whichever is later." While the relevant statutory language literally applies only to the Commission determination of interim operation, the NRC believes that as a matter of logic, Congress must have intended that it would also apply to the threshold question of granting or denying the hearing request. It is unclear why Congress would allow more information to be considered in the threshold question of the hearing request, but limit the information to be considered in the interim operation determination. The NRC concludes that it would be closer to Congress' intention to prohibit a requestor for a § 52.103 hearing from replying to any answers filed by the applicant and/or the NRC staff.

Finally, in a conforming change associated with the revision to § 52.103(c), paragraph (i) is revised to prohibit any "appeal" under § 2.311 of a Commission decision to grant or deny a request for hearing. Inasmuch as the Commission is acting as a presiding officer, there can be no further "appeal" to a higher agency decisionmaker. Moreover, an adversely affected party may seek reconsideration of the Commission's decision under § 2.345, and it would be duplicative to afford an adversely-affected party a § 2.311 "review" right in addition to the opportunity to seek reconsideration under § 2.345.

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

14. Section 2.310, Selection of Hearing Procedures

Section 2.310 is revised, in part to conform with the change in 10 CFR 52.103(c), which now provides that the Commission will act as the presiding officer in determining whether to grant or deny a request for hearing with respect to whether acceptance criteria in ITAAC have been or will be met. The revised § 2.310 now provides that the Commission will determine the hearing procedures to be utilized in its determination on a hearing request under § 52.103, as well as the hearing procedures to be utilized in resolving admitted contentions under § 52.103(c) and (g).[8]

Inasmuch as this revision is to the NRC's rules of procedure and practice, the NRC may adopt it in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

15. Section 2.340, Initial Decision in Certain Contested Proceedings; Immediate Effectiveness of Initial Decisions; Issuance of Authorizations, Permits, and Licenses

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

Scope of Presiding Officer's Initial Decision

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

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

> To have a Licensing Board engage in an idle exercise examining issues just for the sake of examination—when the parties have not raised such matters, and the Board is satisfied that there is nothing to inquire about—would serve no useful purpose. This is particularly true since an operating license proceeding is not to be used to rehash issues already well ventilated and resolved at the construction permit stage. *Alabama Power Co.* (Joseph M. Farley Nuclear Plant, Units 1 and 2), CLI–74–12 (RAI–74–3–203).

Id. at 8. Thus, the limitation was based, in part, upon the broader scope of inquiry for the presiding officer at construction permit stage, which is a "mandatory hearing" required by

[8] The NRC notes that 10 CFR 2.309 does not apply, by its terms, to petitions to modify the terms and conditions of a combined license under 10 CFR 52.103(f). Such petitions must meet the requirements of 10 CFR 2.206.

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Section 189.a(1)(A). This rationale continues to apply today, and consequently the NRC does not propose to alter the NRC's practice by extending the § 2.340(a)/§ 2.760a limitation to construction permit (including early site permit) proceedings. Nor should the § 2.340(a)/§ 2.760a limitation apply in a part 52 combined license proceeding with respect to matters that would otherwise be addressed and resolved in a construction permit issuance proceeding.

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

As discussed previously, the former § 2.340(a)/§ 2.760a limitation applied only to operating license proceedings, and did not apply to other contested proceedings which do not require a "mandatory hearing," which includes most materials licensing proceedings (with the notable exception of the licensing of a uranium enrichment facility). The statement of consideration in this document merely states that the rule codifies the Commission's Indian Point decision. (see January 17, 1975; 40 FR 2973 (first column)). Inasmuch as the Indian Point proceeding involved a utilization facility license, it is likely that the Commission simply did not consider as part of the rulemaking the possibility of applying the limitation to non-production or utilization facility proceedings, as opposed to making a deliberate decision not to apply the limitation to non-production or utilization facility proceedings. Currently, the NRC believes that with 30 additional years of hearing experience, there is no practical, compelling policy-based, or legal reason why the § 2.340(a) limitation should not be extended to non-production or utilization facility proceedings. Accordingly, the NRC is revising § 2.340 by adding a new paragraph (e), which extends the existing limitation on the presiding officer's initial decision in contested proceedings to all other proceedings not covered by paragraphs (a) or (b) of § 2.340. Although this change is not related to the part 52 rulemaking effort, the NRC is adopting this change as part of the part 52 final rule to ensure that stakeholders understand the provisions of § 2.340 as an integrated whole.

Immediate Effectiveness of Presiding Officer's Initial Decision in Production and Utilization Facility Proceedings

The remainder of former § 2.340 was an amalgam of the Commission's original rule (10 CFR 2.764[9]) a presiding officer's initial decision in certain proceedings was immediately effective upon issuance, combined with newer provisions—first adopted in 1979 and modified in 1981—which suspended the immediate effectiveness rule. The "automatic stay" provisions were adopted following the accident at TMI–2, in order to provide for the Commission's direct involvement in the issuance of nuclear power plant licenses. The Commission first issued an *Interim Statement of Policy and Procedure* in October 1979, which first noted that the TMI–2 accident was being investigated by the NRC and may result in "significant changes in the Commission's regulatory policy and in the procedures it employs to license nuclear power facilities." The Policy Statement then indicated that "new construction permits, limited work authorizations, or operating licenses for any nuclear power plants shall be issued only after action of the Commission itself." (See October 10, 1979; 44 FR 58559.) Soon thereafter, on November 9, 1979 (44 FR 65049), the NRC issued a *Suspension of § 2.764 and Statement of Policy on the Conduct of Adjudicatory Proceedings.* As part of this final rulemaking, the NRC adopted a new appendix B to part 2 addressing the suspension of immediate effectiveness provisions in § 2.764, and providing for both Atomic Safety and Licensing Appeal Board review and Commission review of the presiding officer's initial decision.

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

[9] 31 FR 12774 (September 30, 1966).

While the NRC's 1979 and 1981 rulemakings were justified in light of the circumstances at that time, other factors now lead the NRC to believe that the oversight provisions adopted in 1981 are no longer necessary or desirable. In the 25 years since the adoption of the 1981 provisions, the NRC's regulatory framework and requirements for nuclear power plants has evolved and strengthened. The NRC's technical requirements for nuclear power reactors were substantially augmented in the years immediately following the TMI accident, and thereafter have evolved to reflect lessons learned, new information, and the increasing acceptance of risk-informed methodologies. Similarly, the NRC's oversight of nuclear power plants has evolved to reflect lessons learned, new information, and the maturation of risk assessment methodologies. Thus, the NRC believes its regulations may be revised to remove the regulatory requirement for direct Commission involvement in all production and utilization licensing proceedings. The Commission's words in the May 1981 final rulemaking apply with more force today:

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

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

By removing the "automatic stay" provisions in former § 2.340(f) and (g), the NRC's administrative process will be completed in less time, thereby benefitting all parties from the reduction in litigation resources without compromising the fairness of the overall hearing process. Faster completion of

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the adjudication will also enable aggrieved parties to more quickly seek relief via an appeal to a U.S. Circuit Court of Appeals. The NRC believes that Congress intends the Commission to conduct fair, but efficient, hearings with respect to licensing, and to remove unnecessary hearing procedures which do not contribute to such a hearing process. This is evidenced by Section 189 of the AEA, as amended by the Energy Policy Act of 1992, which directs the Commission to issue, "to the maximum possible extent," a final decision on issues raised with respect to acceptance criteria by the anticipated date for initial loading of fuel. The Commission concludes that the changes to § 2.340 are consistent with applicable law, and will provide tangible benefits to all parties in NRC adjudications.

Immediate Effectiveness of Presiding Officer's Initial Decision in Other, Non-Production or Utilization Facility Proceedings

As noted previously, the 1981 final rulemaking provided for an "automatic stay" to provide for direct Commission involvement in the issuance of nuclear power plant licenses. Since that time, the NRC has extended the "automatic stay" provisions in § 2.340 to other licensing contexts, such as independent spent fuel storage facilities (ISFSIs) at sites away from nuclear power reactors, monitored retrievable storage (MRO) licenses, and provided for a parallel provision in 10 CFR part 61 for low-level waste (LLW) facilities, see 10 CFR 2.1211. The NRC did not explain the basis for requiring direct Commission involvement in the issuance of a part 61 LLW license (see 47 FR 57446; December 27, 1982), although one could surmise from the timing of the rulemaking that the factors underlying the 1981 rulemakings also were the basis for the 1982 rulemaking's provision providing for direct Commission involvement in part 61 license issuances. The NRC's original intent in requiring direct Commission involvement in the issuance of specific ISFSI licenses and a MRS license was the lack of regulatory experience (see, e.g., 60 FR 20879 and 20883; April 28, 1995), and, therefore, is somewhat different from the motivating factors for the 1981 rulemakings. In any event, the NRC now has had the benefit of experience in licensing a specific ISFSI, as well as several specific ISFSIs located at reactor sites. Thus, the NRC has come to a recognition that the safety, security and regulatory issues associated with these licenses are of less complexity than those associated with nuclear power plants, and that the NRC has greater time to respond to potentially adverse situations. Compare 46 FR 47764, 47765 (issuance of licenses for activities involving minimal risk to public health and safety, and greater time to take corrective action, do not require Commission involvement). Furthermore, the Commission possesses general supervisory authority over the NRC staff and may direct the staff to keep the Commission appraised of licensing status and issues for such licenses. Accordingly, the NRC concludes that there is little regulatory benefit to be provided by a rule requiring direct Commission involvement in the issuance of these licenses and that the provisions in § 2.340 providing for such involvement should also be removed as part of this streamlining of the regulatory process.

Issuances of Authorizations, Permits, Licenses, and § 52.103(g) Findings

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

Paragraph (i) authorizes the Director of Nuclear Reactor Regulation (NRR) or the Director of the Office of New Reactors (NRO), as appropriate, to issue nuclear power plant licenses, including amendments, permits and authorizations, within 10 days of the initial decision. Paragraph (j) authorizes the Commission or the appropriate staff Office Director to make the finding under 10 CFR 52.103(g) that the acceptance criteria in a combined license have been met. Finally, paragraph (k) addresses the issuance of other licenses that are issued by the Director of Nuclear Material Safety and Safeguards (NMSS). Typical licenses of this type would be materials licenses for, *inter alia,* medical uses, well logging, radiography, irradiators, and research.

16. Section 2.341, Review of Decisions and Actions of a Presiding Officer

This section addresses requests for review and appeals to the Commission from a presiding officer's decision or actions in a hearing. In a conforming change associated with the revision to § 52.103(c), paragraph (a)(1) of § 2.341 is revised to explicitly prohibit a party from seeking a "review" or an "appeal" of the Commission's determination to allow a period of interim operation under § 52.103(c), separate from and in addition to a request for reconsideration under § 2.345. Inasmuch as the Commission is acting as the presiding officer in the § 52.103(c) determination, there can be no further "appeal" to a higher agency decisionmaker. Moreover, it would be duplicative to afford a § 2.341 "review" or "appeal" right in addition to the opportunity to seek reconsideration under § 2.345.

Inasmuch as this revision is to the NRC's rules of procedure and practice, the NRC may adopt it in final form without further notice and comment, under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

17. Section 2.347, Ex Parte Communications

Section 2.347, which sets forth the NRC's requirements governing *ex parte* communications with the Commission and its adjudicatory employees, is revised in this final rule to address several problems with the current rule.

First, § 2.347 is revised to make clear that *ex parte* communication restrictions are not applicable in uncontested proceedings. The APA requirements in 5 U.S.C. 557(d)(1) governing *ex parte* communications apply only to communications "relevant to the merits of the proceeding * * *," which are made to and from "interested persons outside the agency." In an uncontested proceeding, there are no "interested persons outside the agency," in the sense that there are no persons for which a hearing has been requested or intervention in a hearing has been granted. Hence, *ex parte* communication restrictions do not apply. Moreover, as the NRC has stated in the 2004 rulemaking revising 10 CFR part 2, Section 189 of the AEA does not require NRC hearings under that section to be "on the record." See 69 FR 2183–2185, 2192–2193 (January 14, 2004).

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Accordingly, § 2.347 is revised to explicitly provide that *ex parte* restrictions do not apply to uncontested proceedings.

Second, § 2.347 is revised to exclude undisputed (i.e., uncontested) issues in contested proceedings from the application of *ex parte* restrictions. It makes little sense to require the Commission to inform parties to the proceeding of the Commission's communications with the applicant or licensee on matters for which those parties have not been admitted (and may have no interest in litigating). In addition, the NRC believes that uncontested matters are not, for purposes of applying the *ex parte* limitations in Section 557(d)(1) of the APA, either "a fact in issue" or a matter which is "relevant to the merits of the [contested] proceeding." The NRC also believes, as stated above, that the *ex parte* limitations in Section 557(d) of the APA do not apply to NRC proceedings, and therefore the application of *ex parte* restrictions in NRC proceedings is a matter of discretion on the part of the NRC. The NRC believes that it is appropriate to exclude undisputed issues from the application of *ex parte* limitations in contested proceedings, inasmuch as there appears to be little, if any, public confidence benefit from extending *ex parte* limitations to "undisputed issues," i.e., matters which have not been raised by any party in the proceeding.

Finally, § 2.347 is also revised to make clear that *ex parte* restrictions apply to matters which are the subject of a presiding officer referral to the Commission under § 2.340(a), and the presiding officer's examination of that matter following Commission approval under § 2.340(a) (referred to as "*sua sponte*" issues at 53 FR 10361; March 31, 1988). The application of *ex parte* restrictions to § 2.340(a) "*sua sponte*" matters does not represent a change in NRC practice, cf., 53 FR 10360, 10361 (first and second column) (March 31, 1988). Nonetheless, upon further reflection the NRC believes it is inaccurate to treat § 2.340(a) "*sua sponte*" matters as a "disputed issue" for purposes of applying § 2.347. Accordingly, the NRC is revising § 2.347 to explicitly state that consideration of § 2.340(a) "*sua sponte*" matters are to be subject to *ex parte* restrictions.

Inasmuch as these § 2.347 revisions are to the NRC's rules of procedure and practice, the NRC may adopt them in final form without further notice and comment under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

18. Section 2.348, Separation of Functions

This section sets forth the NRC's requirements governing separation of functions of the Commission and its adjudicatory employees when acting in their adjudicatory capacity. The rule prohibits an NRC officer or employee engaged in the performance of investigative or litigation function in that proceeding from participating in or advising the Commission and its adjudicatory employees about "any disputed issue in that proceeding * * *," with certain delineated exceptions (10 CFR 2.348(a)).

The NRC believes that there are two problems with the current language. First, the rule does not explicitly state that in an uncontested proceeding, separation of functions does not apply. More importantly, the rule applies separation of functions in circumstances where it is not required by Section 554(d), viz., determinations involving initial licenses (5 U.S.C. 554(d)(2)(A) of the APA). The NRC recognizes that public confidence considerations may favor compliance with separation of functions restrictions in contested initial licensing proceedings. However, there is little apparent value in applying separation of functions to the NRC's resolution of uncontested (i.e., "undisputed") issues in contested proceedings. The NRC also notes that (as in the case of the APA restrictions on *ex parte* communications) the APA separation of functions requirements apply only to adjudications which are required to be "on the record." As discussed above, NRC licensing proceedings are not required by the AEA or any other statute to be on the record. Thus, there is no legal requirement to apply separation of functions in initial licensing proceedings. Although the NRC could voluntarily, as a matter of discretion, apply separation of functions in circumstances where it is not required by law, such a course of action seems unjustified in view of the lack of a clear public confidence benefit—which is the primary objective of separation of functions restrictions. For these reasons, the final part 52 rule revises § 2.348 to make explicit that separation of functions requirements do not apply to either uncontested proceedings, or to an undisputed issue in contested initial licensing proceedings.

Section 2.348 is also revised to make clear that separation of functions applies to matters which are the subject of a presiding officer referral to the Commission under § 2.340(a), and the presiding officer's examination of that matter following Commission approval under § 2.340(a). As with the change in § 2.347 with respect to *ex parte* restrictions, this change in § 2.348 does not depart from the NRC's current practice of applying separation of function restrictions to "*sua sponte*" matters under § 2.340(a). The NRC believes that it is more accurate to explicitly state that *sua sponte* matters under § 2.340(a) are subject to separation of functions restrictions, rather than characterizing such matters as "disputed issues."

Inasmuch as these § 2.348 revisions are to the NRC's rules of procedure and practice, the NRC may adopt them in final form without further notice and comment under the rulemaking provisions of the APA, 5 U.S.C. 553(b)(A).

19. Section 2.390, Public Inspections, Exemptions, Requests for Withholding

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

20. Subpart D—Additional Procedures Applicable to Proceedings for the Issuance of Licenses To Construct and/or Operate for Nuclear Power Plants of Identical Design at Multiple Sites

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

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(appendix N in part 50 will continue to address proceedings for construction permits and operating licenses under that part).

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

21. Section 2.400, Scope of Subpart

This section is revised to refer to both appendix N of both part 50 and part 52, in order to reflect the Commission's determination that the appendix should be retained in both parts, and that the procedures in the appendices (both of which refer to this subpart) should apply to applications for construction permits, operating reactors, and combined licenses of identical design. In addition, § 2.400 is revised to use the term "identical design," instead of the former "essentially the same design," so that subpart D and appendix N of part 50 and part 52 use identical terminology.

22. Section 2.401, Notice of Hearing on Construction Permit or Combined License Applications Pursuant to Appendix N of 10 CFR Parts 50 or 52

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

23. Section 2.402, Separate Hearings on Separate Issues; Consolidation of Proceedings

Both paragraphs of this section are revised to refer to applications under part 50 and part 52. No other substantive changes are intended by this revision.

24. Section 2.403, Notice of Proposed Action on Applications for Operating Licenses Pursuant to Appendix N of 10 CFR Part 50

This section is revised to refer to operating licenses issued under part 50, rather than part 52. This reflects the Commission's determination that appendix N of part 50 applies to construction permits and operating licenses, whereas appendix N of part 52 applies to combined licenses under subpart C of part 52.

25. Section 2.404, Hearings on Applications for Operating Licenses Pursuant to Appendix N of 10 CFR Part 50

This section is revised to make clarifying changes by adding references to a presiding officer, correctly referring to the Chief Administrative Judge, and removing a reference to the atomic safety and licensing board. No substantive changes are intended by this revision.

26. Section 2.405, Initial Decisions in Consolidated Hearings

This section is revised by requiring the presiding officer to issue a separate partial initial decision on the common design. Section 2.405 is also revised by clarifying that the presiding officer may, if otherwise determined under the consolidation provisions of § 2.317(b), issue a consolidated decision for those proceedings. No other substantive changes are intended by this revision.

27. Section 2.406, Finality of Decisions on Separate Issues

This section is revised to refer to both appendix N of both part 50 and part 52. No other substantive changes are intended by this revision.

28. Section 2.407, Applicability of Other Sections

This section is revised to correctly reference subparts C, L, and N of part 2. No other substantive changes are intended by this revision.

29. Section 2.500, Scope of Subpart

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

30. Section 2.501, Notice of Hearing on Application Under Subpart F of Part 52 for a License To Manufacture Nuclear Power Reactors

This section is revised by adding a conforming reference to subpart F of part 52 on manufacturing licenses. In addition, paragraph (b) of this section is revised by removing the detailed requirements governing the content of the notice of hearing published in the **Federal Register**, and instead referencing proposed § 2.104(f). As previously discussed, the Commission is consolidating in § 2.104 the requirements governing the content of a notice of hearing with respect to part 52 licensing and regulatory approval processes (with the exception of standard design certifications, which are addressed in subpart H of part 2).

31. Sections 2.502, 2.503, and 2.504

The text of these sections is removed, and their places are reserved in the final rule, because the matters addressed in these sections, regarding finality and the referencing of a manufactured reactor in a combined license, are addressed with greater specificity in the revisions to subpart F of part 52.

32. Subpart F, Additional Procedures Applicable to Early Partial Decisions on Site Suitability Issues in Connection with an Application for a Construction Permit or Combined License for Certain Utilization Facilities

Subpart F provides special procedures for the acceptance, docketing, administrative consideration, the conduct of hearings, and the presiding officer's issuance of a partial initial decision in licensing proceedings where there is early submittal of site suitability information in connection with an application for a construction permit or operating license, as described in § 2.101(a–1). As discussed earlier, the NRC has revised § 2.101(a–1) to allow applicants for combined licenses under part 52, as well as applicants for construction permits under part 50, to submit their applications in two parts, and to allow for early consideration and presiding officer's partial initial decision on those site suitability matters for which the applicant seeks early resolution in accordance with subpart F of part 2.

The NRC has reorganized subpart F in an attempt to improve its usability (the reorganization is reflected in the provisions of § 2.600, Scope of subpart). Requirements applicable to partial decisions in construction permit proceedings continue to be addressed in §§ 2.602 through 2.606; a new subheading is added before § 2.602 to reflect the subject matter of these sections. The new requirements applicable to partial decisions in combined license proceedings are in §§ 2.621 through 2.629; a new subheading is also added before § 2.621 to reflect the subject matter covered by these sections. Section 2.629, which has no analogous provisions in §§ 2.602 through 2.606, is added by the NRC to ensure that the finality of a presiding officer's partial initial decision in a combined license proceeding is clearly addressed using regulatory language similar to that used in the finality provisions in part 52, e.g., §§ 52.39, 52.63, 52.98.

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Section 2.601 is revised to correctly list subparts A, C, G, L, and N of part 2 as subparts which are either applicable to or may be utilized in proceedings under subpart F.

33. Section 2.800, Scope and Applicability

Subpart B of part 52 sets out the requirements applicable to Commission issuance of regulations granting standard design certification for nuclear power facilities. Standard design certifications are approved through a rulemaking proceeding, and, in concept, the applicant for a design certification may be considered as a petitioner for rulemaking. However, subpart H of part 2, which sets forth the Commission's procedures governing rulemaking, including petitions for rulemaking, did not specifically address design certification. Furthermore, based upon the Commission's experience with three final design certification rules and a proposed design certification rule, it is clear that some of the procedural requirements applicable to petitions for rulemaking are not well-suited to the administrative process for determining a design certification application, e.g., the existing prohibition against pre-application consultation with the NRC. These consultations between potential license applicants and the NRC staff are not currently prohibited and indeed are encouraged by the Commission to enhance NRC resource planning and to facilitate early identification and resolution of technical and regulatory issues. An application for design certification is more like a license application than a traditional petition for rulemaking, and the current prohibition against pre-application consulting appears to be inconsistent with the Commission's strategic objectives of safety, effectiveness, and management excellence. The Commission also believes, based upon its experience, that administrative provisions ordinarily applied in the context of licensing (e.g., docketing and acceptance review, denial of application for failure to supply information), should also be available for application as appropriate in its determination of design certification applications.

For these reasons, the Commission is revising subpart H of part 2 to address standard design certifications. Section 2.800 is revised to delineate which provisions of subpart H are applicable to all petitions for rulemaking, and which provisions are applicable only to initial applications for design certification and applications for amendments to existing design certification rules filed by the original applicant (or successors in interest). The title of § 2.800 is revised to reflect the additional function of this section. New §§ 2.811 through 2.819 are added to address initial applications for design certification as well as applications for amendments to existing design certifications filed by the original applicant (or successors in interest), and are based upon §§ 2.101, 2.107, and 2.109. Petitions for amendment of existing design certification, which are filed by third parties other than the original applicant for that design certification (or successor in interest), will be treated as an amending petition for rulemaking under the provisions of §§ 2.801 through 2.810.

34. Section 2.801, Initiation of Rulemaking

In a conforming change, § 2.801 is revised to refer to applications for standard design certification rulemaking.

35. Section 2.811, Filing of Standard Design Certification Application; Required Copies

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

36. 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.

37. 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.

38. 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.

39. 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

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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.

40. Section 2.1202, Authority and Role of NRC Staff

Paragraph (a) of § 2.1202 acknowledges and confirms the authority of the NRC staff to take regulatory (including licensing) action during the pendency of a hearing, with several delineated exceptions in numbered paragraphs (a)(1) through (5). Most of these exceptions are mandated by Section 189.a.(1)(A) of the AEA, which requires that the NRC hold a "mandatory hearing," after 30 days notice and publication once in the **Federal Register**, on any application for a construction permit for a facility to be licensed under Section 103 or 104b. Paragraph (a)(1) is revised by adding specific references to applications for limited work authorizations and combined licenses under 10 CFR part 52. A limited work authorization is considered to be a partial construction permit, and a combined license under part 52 includes a construction permit. Therefore, they are both subject to the strictures of Section 189.a.(1)(A). Paragraphs (2), (3), and (4) are redesignated as paragraphs (4), (5), and (6), and a new paragraph (2) is added for early site permits applications. An early site permit is considered to be a partial construction permit, and therefore is also subject to Section 189.a(1)(A). A new paragraph (3) is added for manufacturing licenses, as a matter of NRC discretion. The Section 189.a.(1)(A) requirement for a mandatory hearing applies only to construction permits; a manufacturing license is not a construction permit. Hence, the remaining provisions of Section 189.a.(1)(A), including the NRC's authority to issue an operating license or amendment to a construction permit without a hearing but only upon 30 days notice and publication once in the **Federal Register** of the NRC's intent to do so, are inapposite and do not constrain the NRC's authority to issue manufacturing licenses despite a pending hearing. Nonetheless, as a matter of discretion, the NRC has decided to treat manufacturing licenses similar to construction permits in this regard, although the NRC reserves the right to change its practice in the future.

G. Changes to 10 CFR Part 10

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

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

Section 10.1 is revised by adding a new paragraph (a)(3), which refers to the eligibility of individuals for employment with NRC licensees and applicants, and holders of standard design approvals under part 52. Section 10.2(b) is revised so that it refers to standard design approvals under part 52 and applicants for consultants. This change will address the provision of services associated with design approvals, who may not, per se, be "employees."

H. Changes to 10 CFR Part 19

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

The NRC has identified a number of weaknesses with the former regulatory language in part 19. Formerly, part 19's regulatory requirements and proscriptions applied only to licensees who receive, possess, use or transfer material licensed under the NRC's regulations, including persons licensed to operate a production or utilization facility under 10 CFR part 50, but did not cover holders of 10 CFR part 52 licenses such as combined licenses, early site permits, and manufacturing licenses. Moreover, part 19 applied only to licensees who receive, possess, use or transfer materials licensed under 10 CFR parts 30 through 36, 39, 40, 60, 61, 63, 70 or 72 (including persons licensed to operate a production or utilization facility under part 50). Thus, the former regulations did not appear to address discrimination against an employee during "non-operational" activities such as manufacturing or construction of a nuclear power plant. Because the NRC's regulatory scheme relies upon the proper design, manufacture, siting, and/or construction of a production or utilization facility; discrimination against an employee at any of these stages could have significant adverse public health and safety or common defense and security implications and effects. One would therefore expect that part 19 would apply to such non-operational activities. Finally, part 19 applied only to a "licensee" and activities authorized by a "license" (see, *e.g.*, §§ 19.1, 19.2, 19.11, 19.20, 19.32), and did not extend to part 52's non-licensing regulatory approvals, *i.e.*, standard design approvals and standard design certifications. Inasmuch as these non-licensing activities regulated under part 52 are not different in kind from the licensing which are currently subject to part 19 requirements, the NRC concludes that they should also be subject to the requirements in part 19.

Accordingly, the NRC is amending various provisions in part 19 to ensure that its provisions extend to applicants for and holders of part 50 construction permits, and combined licenses, early site permits and manufacturing licenses under part 52. In addition, the NRC extends part 19 to cover applicants for and holders of standard design approvals and standard design certifications. The NRC believes that its regulatory authority under Section 211 and Section 401 of the 1974 ERA is much broader than the former scope of part 19. The anti-discrimination proscriptions in Section 211 of the ERA apply to any "employer," which the NRC regards as including non-licensee entities otherwise regulated by the NRC, such as applicants for and holders of standard design approvals, and applicants for standard design certifications. The Commission believes that the use of the term, "includes," in paragraph (a)(2) of Section 211 of the 1974 ERA was not intended to be an exclusive list of the persons and entities subject to the anti-discrimination provisions in that section. The House Report on H.R. 776, which was adopted by Congress as the Energy Policy Act of 1992, states:

[Title V] also broadens the coverage of existing whistle blower protection provisions to include * * * *any other employer* engaged

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in *any activity* under the Energy Reorganization Act of the Atomic Energy Act of 1954. (H. Rep. No. 102–474, part 8, 102d Congress, 2d Sess., at 78–79 (1992) (emphasis added))

There was no discussion of the statutory language in the conference report. (H.R. Conf. Rep. No. 102–1018, 102d Cong., 2d Sess. (1992)). The provisions in Section 401 of the ERA, prohibiting sex discrimination apply to "any program or activity carried on * * * under any title of this Act." Accordingly, the NRC concludes that it has the authority to extend the former scope of part 19 to address the non-licensing regulatory approvals in part 52.

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

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

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

Section 19.31, governing exemptions from part 19, is revised to use language consistent with § 50.12 and § 52.7. Unlike the former regulation, which limits a request for exemption to a "licensee," the final rule allows "interested persons," as well as licensees to request an exemption from one or more provisions of part 19. This will allow applicants for and holders of non-license regulatory vehicles in part 52 (standard design approvals and design certifications) to request exemptions from part 19. The broadened scope of persons that will be allowed to request an exemption is consistent with most of the exemption provisions throughout the NRC's regulations in Title 10 of the CFR, including the specific exemption provision in part 50 (*i.e.*, § 50.12).

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

I. Changes to 10 CFR Part 20

1. Section 20.1002, Scope

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

2. Section 20.1401, General Provisions and Scope

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

3. Section 20.1406, Minimization of Contamination

Section 20.1406 requires applicants for licenses, other than renewals, after August 20, 1997, to describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. The NRC is adding conforming changes to § 20.1406 in the final rule. These conforming changes to address part 52 were inadvertently overlooked in the proposed rule. Section 20.1406 contains requirements that relate both to design and operation of a facility and therefore applies in whole or in part to design approvals, design certifications, manufacturing licenses, and combined licenses. The final rule divides § 20.1406 into two paragraphs. Paragraph (a) addresses applicants for licenses, other than early site permits and manufacturing licenses, and contains all of the requirements in former § 20.1406. Paragraph (b) addresses applicants for standard design certifications, standard design approvals, and manufacturing licenses and only contains the requirements related to design. If a combined license applicant references a design approval, design certification, or a reactor manufactured under a manufacturing license that has addressed the design portion of this requirement under paragraph (b), then it would only need to address the remaining "operational" requirements under paragraph (a).

4. Section 20.2203, Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits

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

J. Changes to 10 CFR Part 21

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

Key Principles of Reporting Under Section 206 of the ERA

The NRC believes that the extension of NRC's reporting requirements

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implementing Section 206 of the ERA to part 52 licensing and approval processes should be consistent with three key principles. First, NRC regulatory requirements implementing Section 206 of the ERA should be a legal obligation throughout the entire "regulatory life" of an NRC license, a standard design approval, or standard design certification. Second, reporting of defects or failures to comply associated with substantial safety hazards should occur whenever the information on potential defects would be most effective in ensuring the integrity and adequacy of the NRC's regulatory activities under part 52 and the activities of entities [10] subject to the part 52 regulatory regime. Third, each entity conducting activities within the scope of part 52 should develop and implement procedures and practices to ensure that it fulfills its Section 206 of the ERA reporting obligation in an accurate and timely manner.

First Principle—Section 206 of the ERA Applies Throughout "Regulatory Life"

The first principle, that NRC regulatory requirements implementing Section 206 must extend throughout the entire "regulatory life" of a part 52 process, reflects the regulatory pattern inherent in part 52, whereby certain designated licenses or approvals—e.g., an early site permit, nuclear power reactor manufactured under a manufacturing license, or a design certification—are capable of being referenced in a subsequent nuclear power plant licensing application. Under the part 52 regulatory scheme, a referenced NRC approval constitutes the NRC's basis for the licensing action within the scope of the prior Commission approval, and becomes part of the "licensing basis" for that plant. However, if Section 206 of the ERA reflects that effective NRC decision-making and regulatory oversight require accurate and timely information about defects and failures to comply associated with substantial safety hazards, then Section 206 of the ERA should apply whenever necessary to support effective NRC decision-making and regulatory oversight of the referencing licenses and regulatory approvals. To put it in different terms, if the NRC decision that it may safely issue a license depends in part upon an earlier NRC safety determination for a referenced license, standard design approval, or standard design certification, it follows that a safety issue with respect to the referenced license, design approval, or design certification has safety implications for the referencing license or design certification, and the continuing validity of the NRC's licensing decision. Thus, the NRC concludes that the need for Section 206 reporting should not be limited to those licenses and approvals under part 52 which are referenced or "relied upon" in a subsequent nuclear power plant licensing application (viz., early site permits, standard design approvals, standard design certifications, and manufacturing licenses), but rather should extend to licenses and approvals that are capable of being referenced in a future licensing application. In other words, they must extend until there can be no further potential safety implications for a referencing license or approval.

The NRC believes that the beginning of the "regulatory life" of a referenced license, standard design approval, or standard design certification under part 52 occurs when an application for a license, design approval, or design certification is docketed. Docketing of an application marks the start of the NRC's formal safety and environmental review of the application, and therefore the initiation of the NRC's need for accurate and timely information to support its regulatory review and approval. However, the NRC cautions that this does not mean that an applicant is without Section 206 responsibilities for pre-application activities. As the NRC staff discussed in a June 22, 2004, letter to the Nuclear Energy Institute (NEI) (ML040430041) in the context of an early site permit, there are two aspects, namely, a "backward looking" or retrospective aspect with respect to existing information, and a "forward looking" or prospective aspect with respect to future information. The retrospective obligation is that the early site permit holder and its contractors, must report all known defects or failures to comply in "basic components," as defined in part 21. The prospective obligation is that the early site permit holder and its contractors must report all defects or failures to comply in basic components discovered subsequent to early site permit issuance. The early site permit holder and its contractors are required to meet these requirements, and must continue to meet them throughout the term of the early site permit. Accordingly, safety-related design and analysis or consulting services should be procured and controlled, or dedicated, in a manner sufficient to allow the early site permit holder and its contractors, as applicable, to comply with the above described reporting requirements of Section 206, as implemented by 10 CFR 50.55(e) and part 21.

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

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

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

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satisfy the NRC's regulatory objectives, it is not adopted.

One of the original applicants for the current standard design certifications stated that any arguable Section 206 requirements must logically end upon expiration of the standard design certification, inasmuch as expiration marks the end time that the standard design certification may be referenced. The NRC disagrees with this position. Under § 52.55(b) of the current regulations, a standard design certification continues to be effective in a hearing for a combined license or operating license docketed before the expiration date, and in a hearing under § 52.103 for authority to load fuel and operate. At minimum, the original standard design certification applicant should be subject to Section 206 requirements until the proceeding is completed. Beyond the minimum requirements, the NRC also believes that the original design certification applicant's Section 206 obligations should continue until operation is no longer authorized in accordance with § 50.82(a)(2) for the last operating license or combined license referencing that standard design certification. The NRC believes that the regulatory need for information concerning defects in a standard design certification continues throughout the operating life of a license referencing that design certification; the relevance of and the NRC's need for this information, if subsequently discovered by the original design certification applicant, does not diminish simply because the standard design certification may no longer be referenced.

Second Principle—Notification Occurs When Information Is Needed

The second principle is focused on ensuring that the NRC, its licensees, and license applicants receive information on defects at the time when the information would be most useful to the NRC in carrying out its regulatory responsibilities under the AEA, and to the licensee or applicant when engaging in activities regulated by the NRC. A result of this principle is that reporting may be delayed if there is no immediate consequence or regulatory interest in prompt reporting, and that delayed reporting will actually occur when necessary to support effective, efficient, and timely action by the NRC, its licensees and applicants. Applying the second principle and its result to part 52 processes, the NRC believes that immediate reporting is required throughout the period of pendency of an application, be it a license, a standard design approval, or a standard design certification. Allowing an applicant to delay the reporting of a defect would appear to be inconsistent with the NRC's statutory mandate to provide adequate protection to public health and safety and common defense and security. Even if delayed reporting would allow the NRC an opportunity to modify its prior safety finding with respect to the license, design approval, or design certification, the delayed consideration is inconsistent with one of the fundamental purposes of part 52, viz., to provide for early consideration and resolution of issues in a manner that avoids the potential for delay during licensing of a facility. Accordingly, the Commission has determined that the NRC's requirements implementing Section 206 of the ERA must extend to applicants (and their contractors and subcontractors) for all part 52 processes (licenses, early site permits, design approvals, and design certifications). Some commenters stated that part 21 should not apply to applicants and claimed that the NRC's proposal was contrary to the ERA. For the reasons stated previously, the Commission does not agree with that position. However, once an application has been granted, the Commission has decided that immediate reporting of subsequently-discovered defects is not necessary in certain circumstances. For those part 52 processes which do not authorize continuing activities required to be licensed under the AEA, but are intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals, the reporting of defects or failures to comply associated with substantial safety hazards may be delayed until the time that the part 52 process is first referenced. The Commission's view is based upon its determination that a defect with respect to part 52 processes should not be regarded as a "substantial safety hazard," because the possibility of a substantial safety hazard becomes a tangible possibility necessitating NRC regulatory interest only when those part 52 processes are referenced in an application for a license, such as a combined license or manufacturing license.

Some commenters believe that these reporting requirements should not apply to a holder of an early site permit or a vendor of a standard design until the ESP or standard design is referenced in a COL application. As stated previously, the Commission agrees that reporting may be delayed until the approval, certification, or permit is referenced. After referencing, the holder (or in the case of a design certification, the applicant who submitted the application leading to the final design certification regulation) must make the necessary notifications to the NRC as well as provide final engineering. The notification must address the period from the Commission adoption of the final design certification regulation up to the filing of the application referencing the final design certification regulations. Thereafter, notice must be made in the ordinary manner. The notification obligation ends when the last license referencing the design certification is terminated.

Third Principle—Procedures and Practices Must Be Implemented To Ensure Accurate and Timely Reporting

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

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

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Division of Implementing Requirements Between Part 21 and § 50.55(e)

Under the Commission's current regulatory structure, persons and entities engaged in construction (or the functional equivalent of construction) are subject to reporting requirements under § 50.55(e). Persons and entities engaged in all other activities within the purview of Section 206 of the ERA are subject to the requirements in part 21 and/or § 50.55(e). The revised part 21 and § 50.55(e) reflect the Commission's determination to retain this divided regulatory structure. The NRC believes that the only part 52 processes that authorize "construction" or its functional equivalent are manufacturing licenses and combined licenses before the Commission makes the finding under § 52.103(g). Therefore, the reporting requirements with respect to Section 206 of the ERA for manufacturing licenses and combined licenses before the Commission makes the finding under § 52.103(g) are contained in § 50.55(e). The requirements in part 21 apply after the Commission makes the finding under § 52.103(g) for a combined license. Part 21 was revised to explicitly apply to the remaining part 52 processes, i.e., early site permits, standard design approvals, and standard design certifications. Table A–1 provides a summary of the applicability of part 21 and § 50.55(e) to each of the various approvals under part 52.

TABLE A–1.—APPLICABILITY OF NRC REQUIREMENTS IMPLEMENTING SECTION 206 OF THE ENERGY REORGANIZATION ACT TO PART 52 LICENSING AND APPROVAL PROCESSES

Part 52 licensing or approval processes	Applicable NRC requirement implementing section 206 of the ERA	Sanctions	
		Civil	Criminal
Early Site Permit (ESP)			
Application	part 21	21.61	21.62
Issuance of ESP	part 21	21.61	21.62
Standard Design Approval (SDA)			
Application	part 21	21.61	21.62
Issuance of SDA	part 21	21.61	21.62
Standard Design Certification Rule (DCR)			
Application	part 21	21.61	21.62
Final DCR Rulemaking	part 21	21.61	21.62
Combined License (COL)			
Application	50.55(e)	50.110	50.111
COL before § 52.103 Authorization	50.55(e)	50.110	50.111
COL after § 52.103 Authorization	part 21	21.61	21.62
Manufacturing License (ML)			
Application	50.55(e)	50.110	50.111
Issuance of ML	50.55(e)	50.110	50.111

Reporting Requirements for Early Site Permits

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

Some commenters claimed that there is no practicable method for ESP applicants or holders to determine whether an error in siting information creates a substantial safety hazard and, therefore, part 21 should not be applicable to ESP applicants or holders. The Commission does not agree with this position. As stated previously, the ESP holder and its contractors can determine defects or failures to comply with "basic components," as defined in part 21. This information is necessary in order to support effective NRC decisionmaking and regulatory oversight of the referencing licenses and approvals.

Applicability of Part 21 to Contractors or Subcontractors of an ESP Applicant or Holder

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

Reporting Requirements for Standard Design Approvals

A standard design approval represents the NRC staff's determination regarding the acceptability of the design for a nuclear power reactor (or major portions thereof). Although a standard design approval does not represent the NRC's final determination as to the acceptability of the design, it nonetheless represents a substantial expenditure of agency resources in reviewing the design. A standard design

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approval may be referenced in a subsequent application for a design certification, construction permit, operating license, combined license, or manufacturing license. Accordingly, consistent with the first principle, the final rule imposes requirements implementing Section 206 of the ERA on applicants for and holders of standard design approvals.

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

Reporting Requirements for Standard Design Certification Regulations

A standard design certification represents the NRC's approval by rulemaking of an acceptable nuclear power reactor design, which may then be referenced in a subsequent combined license or manufacturing license application. Consistent with the first principle, the Commission imposed Section 206 of the ERA reporting requirements on applicants for design certifications, including applicants whose designs are certified in a final design certification rulemaking. As with a standard design approval, a design certification does not actually authorize construction. Accordingly, the NRC revised §§ 21.2, 21.3, 21.21, 21.51, and 21.61 to explicitly refer to an applicant for a standard design certification, rather than § 50.55(e).

Some commenters have asserted that because there is no "holder" or licensee, the NRC is without authority under Section 206 of the ERA to impose part 21 and/or § 50.55(e) evaluation and reporting requirements on applicants for standard design certification. The NRC disagrees with this assertion. The statute by its terms does not limit its reach to licensees; rather, the statute applies to any individual or responsible officer of a firm "constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated * * *." The NRC believes that an applicant for a standard design certification, by submitting its application, is constructively "supplying" a "component" (the nuclear power plant) for use in a future "facility * * * licensed" by the NRC. One of the consequences of the design certification provisions in part 52 is the ability of the applicant to subsequently offer its design with additional, value-added services. Thus, applying for and facilitating NRC adoption of a final standard design certification regulation is simply a partial step in the overall activity of "supplying" the certified design to potential nuclear power plant license applicants. Alternatively, one could treat the standard design certification applicant as supplying a component of an "activity" which is "otherwise regulated" by the NRC. Under this interpretation, the "activity * * * otherwise regulated by the NRC" can be viewed as the design certification rulemaking, and/or the entire part 52 regulatory regime whereby a design certification rule is referenced in a subsequent licensing application. The NRC concludes that under either interpretation, Section 206 of the ERA provides ample statutory authority for the NRC to impose regulations implementing Section 206 on design certification applicants, during the pendency of the application before the NRC, as well as after NRC adoption of a final design certification regulation (for those applicants whose application is granted).

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

Reporting Requirements for Combined Licenses

A combined license authorizes both construction of a nuclear power plant, and loading of fuel and operation if the NRC makes the findings specified in § 52.103. As such, the application of the first and second principles to combined licenses is the most straightforward of all the part 52 processes. Under the final rule, the NRC's requirements implementing Section 206 of the ERA would apply throughout the regulatory life of the combined license, i.e., from docketing of the application until termination of the combined license.

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

Reporting Requirements for Manufacturing Licenses

Under subpart F of part 52, a manufacturing license would constitute both the NRC's approval of a final nuclear power reactor design, as well as approval to manufacture one or more reactors in accordance with approved programs and procedures. The manufactured reactors would then be transported offsite and incorporated into nuclear power facilities by holders of combined licenses—who may be different entities than the holder of a manufacturing license. Given the possibility that the manufacturing license holder is different from the combined license holder whose facility uses the manufactured reactor, the NRC believes that the combined license holder must be kept informed of any significant issue with design or manufacture of the reactor, to ensure that they evaluate the significance of these matters for their facility and undertake any necessary action to assure public health and safety and common defense and security. Furthermore, unlike a standard design certification, the financial resources necessary to obtain a manufacturing license will, as a practical matter, result in manufacturing beginning immediately after issuance of the manufacturing license. There will be no interim period similar to a design certification where there is no activity occurring under the manufacturing license. Accordingly, in compliance with the first and second principles, the NRC proposes that Section 206 of the ERA requirements should apply continuously from the filing of the application, until the manufacturing license expires or is otherwise terminated by the NRC.

A manufacturing license holder would essentially be conducting the same activities as a construction permit holder, albeit with several differences.[11] 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, are contained in § 50.55(e).

[11] These 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.

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Accordingly, the NRC revised § 50.55(e) to specifically apply its provisions to holders of manufacturing licenses.

K. Change to 10 CFR Part 25

1. Section 25.35, Classified Visits

Part 25 sets forth the NRC's requirements governing the granting of access authorization to classified information to certain individuals. Section 52.35, which requires that licensees and certificate holders minimize the number of classified visits, did not, by its terms, apply to applicants for standard design certifications, and applicants for or holders of standard design approvals. Accordingly, § 25.35 is revised to refer to an applicant for a standard design certification under part 52 (including the applicant after the NRC adopts a final standard design certification rule), and the applicant for or holder of a standard design approval under part 52.

L. Changes to 10 CFR Part 26

1. Section 26.2, Scope, § 26.10, General Performance Objectives; and Appendix A to Part 26

Part 26, which sets forth the NRC's requirements governing fitness-for-duty, currently uses a two-part regulatory regime for the application of fitness-for-duty requirements. A holder of an operating license for a nuclear power plant is required to implement all of the provisions in part 26. By contrast, a holder of a construction permit is required to comply with §§ 26.10, 26.20, 26.23, 26.70, and 26.73, and also implement a chemical testing program, including random tests, and make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and record keeping.

The NRC has extended the applicability of parts 26 to 52, in keeping with the existing two-part regulatory regime, so that the full array of requirements in part 26 apply to a combined license holder after the date that the NRC authorizes makes the finding under § 52.103(g), analogous to holder of an operating license under part 50. By contrast, holders of combined licenses, before the date that the NRC makes the § 52.103(g) findings, are required to comply with the part 26 provisions currently applicable to construction permit holders. Similarly, holders of manufacturing licenses under subpart F of part 52 are treated the same as holders of construction permits. Finally, persons authorized to conduct the limited construction activities allowed under § 50.10(e)(3) are also treated the same as a construction permit holder. The final rule accomplishes this by: (1) Revising § 26.2(a) to refer to combined license holders after the date that the NRC makes the finding under § 52.103(g); (2) revising § 26.2(c) to refer to a holder of a combined license before the date that the NRC makes the finding under § 52.103(g), a holder of a manufacturing license under subpart F of part 52, and a person authorized to conduct the activities under § 50.10(e)(3); (3) revising § 26.10(a) to refer to the personnel of a holder of a manufacturing license and those authorized to conduct the activities under § 50.10(e)(3); and (4) revising appendix A to part 26, paragraph 1.1(1) to include a reference to a holder of combined license after the date that the NRC makes the finding under § 52.103(g).

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

M. Changes to 10 CFR Part 51

The NRC is making several conforming changes to part 51 to clarify the environmental protection regulations applicable to the various part 52 licensing processes.

NEPA Compliance for Design Certifications

For each of the four design certification rules in appendices A, B, C, and D of part 52, the NRC prepared an environmental assessment which: (1) Provides the bases for a Commission finding of no significant environmental impact (FONSI) for issuance of the design certification regulation; and (2) identifies and addresses the need for incorporating SAMDAs into the design certification rule. Based upon this experience, the NRC is making changes to part 51 to accomplish two objectives.

First, the NRC is eliminating the need for the NRC to prepare essentially repetitive discussions in environmental assessments supporting a FONSI on issuance of a final standard design certification regulation. Each of the environmental assessments and 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. The NRC is revising part 51 to eliminate the need for the NRC to make repetitive findings of no significant environmental impact for future design certifications and amendments to design certifications.

Second, the NRC is requiring that SAMDAs be addressed at the design certification stage. SAMDAs are alternative *design* features for preventing and mitigating severe accidents, which may be considered for incorporation into the proposed design. The SAMDA analysis is that element of the severe accident mitigation alternatives analysis dealing with design and hardware issues. At the design certification stage, the NRC's review is directed at determining if there are any cost beneficial SAMDAs that should be incorporated into the design, and if it is likely that future design changes would be identified and determined to be cost-justified in the future based on cost/benefit considerations. It is most cost effective to incorporate SAMDAs into the design at the design certification stage. Retrofitting a SAMDA into a design certification once site-specific design and engineering for a nuclear power facility have been completed would increase the cost of implementing a SAMDA. The retrofitting costs continue to increase in ensuing stages of facility construction and operation. For these reasons, the NRC believes that environmental

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assessments for design certifications should address SAMDAs. However, under the former provisions of part 51, both the environmental information submitted by the design certification applicant, and the environmental assessment prepared by the NRC, are directed either at determining whether an EIS must be prepared, or that a FONSI is justified. Accordingly, the NRC is requiring that SAMDAs be addressed in environmental reports and environmental assessments for design certifications.

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

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

The NRC is revising § 51.50(c)(2) to indicate that if a combined license application references a design certification then the combined license applicant's environmental report may reference the SAMDA discussion in the design certification environmental assessment as part of its SAMDA analysis, but must contain information demonstrating that the site characteristics for the combined license site falls within the site parameters in the design certification environmental assessment.[12]

Finally, the NRC is adding § 51.75(c)(2) to provide that if a combined license application references a design certification, then the combined license EIS will incorporate by reference the design certification environmental assessment, and summarize the SAMDA analysis and conclusions of the environmental assessment.

NEPA Compliance for Manufacturing Licenses

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

Further, the NRC does not believe that NEPA requires the NRC to address the environmental impacts of actually manufacturing a nuclear power reactor licensed under subpart F of part 52, either at the manufacturing license stage or at the combined license stage where an application proposes to use a manufactured reactor. The manufacturing license approves the final design of the manufactured reactor, the organization and technical procedures for designing and manufacturing the reactor, and the ITAAC that are to be used by the licensee in determining whether the reactor has been properly manufactured in accordance with NRC requirements and the manufacturing license, and the possession (but not the use or transport offsite) of the manufactured reactor. The manufacturing license does not approve any specific location, building, or facility where the actual manufacture of the reactors may occur,[13] 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 manufacturing license stage or at the combined license stage where the application proposes to use a manufactured reactor, the speculative impacts of manufacturing a reactor offsite at a location or in a facility not specified or approved in the manufacturing license.

The NRC is making a number of changes to part 51, in some cases parallel to those described previously with respect to design certifications, consistent with its views on manufacturing licenses. The NRC is revising existing § 51.54 to clarify that an environmental report for a manufacturing license must address the costs and benefits of SAMDAs and the bases for not incorporating SAMDAs

[12] The 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.

[13] A 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.

into the design of the reactor to be manufactured, and to state that the environmental report need not address the impacts of manufacturing a reactor under the manufacturing license. The NRC is removing both § 51.20(b)(6), which formerly required preparation of an EIS for issuance of a manufacturing license, and § 51.76, which formerly addressed the subject matter of an EIS for a manufacturing license, from part 51.

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

The NRC is adding § 51.50(c)(3) to provide that if a combined license application proposes using a manufactured reactor, then the combined license environmental report may incorporate by reference the environmental assessment for the manufacturing license under which the reactor is to be manufactured and, if so, must include information demonstrating that the site characteristics for the combined license site fall within the site parameters specified in the manufacturing license environmental assessment. This section also states that the environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

Finally, the NRC is adding § 51.75(c)(3) to indicate that if the proposed combined license application to use a manufactured reactor and the site characteristics of the combined license's site fall within the site parameters specified in the manufacturing license environmental assessment,[14] then the combined license EIS must incorporate by reference the manufacturing license environmental assessment. As in the case where the combined license application references a design certification, § 51.75(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) explicitly provides that the combined license EIS will not address the environmental impacts of manufacturing the reactor under the manufacturing license.

NEPA Obligations Associated With § 52.103(g) Findings on ITAAC

Formerly, neither part 51 nor subpart C of part 52 explicitly addressed whether an environmental finding under NEPA is needed in connection with an NRC finding under § 52.103(g) that combined license ITAAC have been met. Nor does part 51 or subpart C of part 52 explicitly address whether contentions on environmental matters may be admitted in a hearing under § 52.103(b). The NRC never intended to make an environmental finding in connection with the § 52.103(g) finding on ITAAC, and the NRC does not believe that NEPA requires such a finding. The § 52.103(g) finding that ITAAC have been met is not a "major Federal action significantly affecting the environment." The major Federal action occurs when the NRC issues the combined license, which includes the authority to operate the nuclear power plant—subject to an NRC finding of successful completion of ITAAC. This is the reason why the environmental impacts of operation under the combined license are evaluated and considered by the NRC in determining whether to issue the combined license even under the former provisions of part 52, see § 52.89. By contrast, the scope and nature of the NRC finding that ITAAC have been met is constrained by the ITAAC itself (indeed, the NRC has always recognized the possibility that ITAAC could be written such that the "inspections and tests" exception in Section 554(a)(3) of the APA could be invoked to preclude the need to provide an opportunity for hearing on § 52.103(g) findings). The safety consequences of operation are not considered when making the § 52.103(g) findings; these issues are addressed by the NRC in determining whether to issue the combined license in the first place. Therefore, the NRC does not view the § 52.103(g) finding as constituting a "major Federal action," and makes no environmental findings in connection with that finding. It, therefore, follows that no contentions on environmental matters should be admitted in any hearing under § 52.103(b).

Accordingly, the NRC is adding § 51.108 to clarify that: (1) The Commission will not make any environmental findings in connection with the finding under § 52.103(g); and (2) contentions on any environmental matters, including the adequacy of the combined license EIS and any referenced environmental assessment, may not be admitted into any § 52.103(b) hearing on compliance with ITAAC. Those issues are essentially challenges to the continuing validity of the combined license or any referenced design certification or manufacturing license. Accordingly, these challenges should be raised with the Commission using relevant Commission-established processes for requesting Commission action. A challenge on environmental grounds with respect to the combined license or manufacturing license must be filed under the provisions of § 2.206. A challenge to an existing design certification on environmental grounds must be filed as a petition for rulemaking to modify the existing design certification under subpart H of part 2.

NEPA Compliance for Combined Licenses Referencing an Early Site Permit

The NRC has made several changes in the final rule based on public comments regarding the requirements for a combined license application referencing an early site permit and further consideration of the NRC's obligations under NEPA for such actions. Several commenters believed that an ESP and COL met the definition of "connected actions," under NEPA case law and Council on Environmental Quality (CEQ) regulations, and should therefore not require the preparation of a new EIS for the second of the two connected actions, or a revalidation of previous findings if neither the applicant nor others identify new and significant information. Commenters stated that under applicable NEPA case law, there was no requirement to prepare a new EIS for the latter of the two connected actions that were previously evaluated together in a single EIS. The commenters stated that the EIS prepared at the ESP stage serves as the EIS for issuance of both the ESP and COL. Commenters stated that the ESP EIS included an evaluation of the environmental impacts related to

[14] Analogous 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.

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issuance of a COL inasmuch as it considered the environmental impact of plant construction and operation.

The NRC continues to believe that it is not necessary to require that all topics be covered in a single EIS at the ESP stage, and that topics such as alternative energy sources and need for power may be treated in an EIS supplement at the COL application stage when the detailed planning for the project is completed. As the commenters note, new and significant information may also prompt the preparation of a supplement to the ESP EIS in connection with the COL application. Since the NRC believes that some issues may not be ripe for consideration at the ESP stage, and an ESP EIS need not address such issues, the Commission is declining to take a position on whether the granting of an ESP and the granting of a COL referencing that ESP are connected actions. Nevertheless, the Commission believes 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 ESP stage and the NRC staff intends to incorporate by reference the ESP EIS in the combined license supplemental EIS. A description of what the combined license applicant must address in this situation can be found under the discussion of changes to § 51.50(c)(1).

More specific changes to individual sections in part 51 are discussed as follows:

1. Section 51.20, Criteria for and Identification of Licensing and Regulatory Actions Requiring Environmental Impact Statements

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

2. Section 51.22, Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or Otherwise Not Requiring Environmental Review

The NRC is revising § 51.22(c) to identify part 52 licensing processes that are eligible for categorical exclusion or otherwise do not require environmental review.

3. Section 51.23, Temporary Storage of Spent Fuel After Cessation of Reactor Operation—Generic Determination of No Significant Environmental Impact

The NRC is revising §§ 51.23(b) and(c) to indicate that the provisions of these paragraphs also apply to combined licenses.

4. Section 51.26, Requirement To Publish Notice and Conduct Scoping Process

The NRC is adding a new paragraph (d) to this section to provide requirements for publication of a notice of intent when the NRC determines that a supplement to an EIS will be prepared. This new provision also states that, in such cases, the NRC staff need not conduct a scoping process, provided, however, that if scoping is conducted, then the scoping must be directed at matters to be addressed in the supplement. If scoping is conducted in a proceeding for a combined license referencing an ESP under part 52 , then the scoping must be directed at matters to be addressed in the supplement as described in § 51.92(e).

5. Section 51.27, Notice of Intent

The NRC is adding a new paragraph (b) to this section to provide requirements for the contents of a notice of intent when the NRC determines that a supplement to an EIS will be prepared. Paragraph (b) states that the notice of intent will, among other things, describe the matters to be addressed in the supplement to the final EIS and describe any proposed scoping process that the NRC staff may conduct.

6. Section 51.29, Scoping-Environmental Impact Statement and Supplement to Environmental Impact Statement

The NRC is revising paragraph (a)(1) of this section in the final rule to include requirements for supplements to an ESP EIS prepared for a combined license application.

7. Section 51.45, Environmental Report

The NRC is revising § 51.45(c) to indicate that the analysis in an environmental report prepared for an ESP need not include consideration of the economic, technical, and other benefits and costs of the proposed action and of energy alternatives. This change is being made for consistency with the provisions of § 51.50(b), which state that an environmental report included in an ESP application need not include an assessment of the benefits (e.g., need for power) of the proposed action and with the Commission's denial of a Petition for Rulemaking (See PRM–52–02 (October 28, 2003; 68 FR 55905)).

8. Section 51.50, Environmental Report—Construction Permit, Early Site Permit, or Combined License Stage

The NRC is revising the title of § 51.50 to "Environmental Report Construction Permit, Early Site Permit, or Combined License Stage," and including separate paragraphs with specific requirements for environmental reports for early site permit and combined license applications which are based on existing requirements in part 51 for construction permits and operating licenses and requirements for early site permits and combined licenses in part 52.

The NRC is revising the requirements from former § 52.17(a)(2) to clarify that an early site permit applicant has the flexibility of either addressing the matter of alternative energy sources in the environmental report supporting its early site permit application, or deferring consideration of alternative energy sources to the time that the early site permit is referenced in a licensing application. The NRC believes the former regulations already afforded the early site permit applicant such flexibility, inasmuch as former § 52.17(a)(2) stated that the environmental report submitted in support of an early site permit application must "focus on the environmental effects of construction and operation of a reactor, or reactors * * *." The environmental report's discussion of alternative energy sources does not, per se, address the "environmental effects of construction and operation of a reactor," which is one of the matters which must be addressed in an environmental impact statement (EIS). [See 10 CFR 51.71(d); National Environmental Policy Act of 1969 (NEPA), Sec. 102(2)(C)(i), (ii), and (v).] Rather, alternative energy sources constitute part of the discussion of reasonable alternatives to the proposed action, which is required by Section 102(2)(C)(iii) of NEPA. [See 10 CFR 51.71(e) n.4; 46 FR 39440 (August 3, 1981) (proposed rule that would eliminate consideration of need for

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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 alterative energy sources). (Id. at 48 (citations omitted).)

Accordingly, the NRC believes that former § 52.17(a)(2) already provided the early site permit applicant the flexibility of choosing to defer consideration of alternative energy sources to the time that the early site permit is referenced in a combined license or a construction permit application. The revisions in § 51.50(b) clarify that the early site permit applicant may either include a discussion of alternative energy sources in its environmental report, or defer consideration of the matter. The NRC made conforming amendments elsewhere in part 51 to clarify that the NRC's EIS need not address the need for power or alternative energy sources (and therefore these matters may not be litigated) if the early site permit applicant chooses not to address these matters in its environmental report. The environmental report and EIS for an early site permit must address the benefits associated with issuance of the early site permit (e.g., early resolution of siting issues, early resolution of issues on the environmental impacts of construction and operation of a reactor(s) that fall within the site characteristics, and ability of potential nuclear power plant licensees to "bank" sites on which nuclear power plants could be located without obtaining a full construction permit or combined license). The benefits (and impacts) of issuing an early site permit must always be addressed in the environmental report and EIS for an early site permit, regardless of whether the early site permit applicant chooses to defer consideration of the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site. This is because the "benefits * * * of the proposed action" for which the discussion may be deferred are the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site; the benefits which may be deferred are entirely separate from the benefits of issuing an early site permit. The proposed action of issuing an early site permit is not the same as the "proposed action" of constructing and operating a nuclear power plant for which the discussion of benefits (including need for power) may be deferred under § 51.50(b).

The NRC is further modifying § 51.50(b) in the final rule based on public comments. This section addresses requirements for environmental reports at the early site permit stage. In the proposed rule, § 51.50(b) stated that environmental reports "must focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the postulated site parameters." Commenters pointed out that the use of "postulated site parameters" was not consistent with the terminology the NRC had used elsewhere in the proposed rule. Consequently, the NRC is revising this provision in the final rule to require that the environmental report "must focus on the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application." A similar change is being made to the same language in final rule § 51.75(b) [proposed § 51.71(d)].

The NRC is making additional changes to § 51.50(b) to further clarify the scope of the environmental review at the early site permit stage. Final § 51.50(b)(2) states that an early site permit environmental report may address one or more of the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, but that the environmental report must address all environmental effects of construction and operation necessary to determine whether there is any obviously superior alternative to the site proposed. The purpose of this change is to clearly delineate that the scope of the environmental review at the early site permit stage is, at a minimum, to address all issues needed for the NRC to perform its evaluation of the alternative sites. In addition, the applicant may choose to address one or more issues related to construction and operation of the facility with the goal of achieving finality on those issues at the early site permit stage.

In addition, the NRC is modifying §§ 51.50(b) and 51.50(c) in the final rule to reflect comments made at the NRC's public workshops during the public comment period on the proposed rule. These discussions related to the requirement to include a proposed list of activities and a redress plan in license applications that request authority to perform activities under § 50.10(e). The NRC concluded that it is preferable to include both the list of proposed activities and the redress plan as separate documents in the application, outside of both the final safety analysis report (or site safety analysis report in the case of an early site permit) and the environmental report. The NRC's conclusion is based on the fact that the requirements in § 50.10(e) address both safety and environmental issues. Additional changes were made to §§ 52.17(c), 52.79(a), and 52.80 to implement this concept.

The NRC is also revising § 51.50(c) based on public comments in the final rule. These revisions address the situation where a combined license applicant is referencing an early site permit and provide for a clearer link to the finality provisions in § 52.39, eliminate language that attempted to define "new and significant," and provide greater consistency with related requirements elsewhere in part 51. The revisions also provide requirements for addressing environmental terms and conditions. The discussion that follows reflects the language in the final rule.

The NRC is adding a requirement in § 51.50(c)(1) that the applicant's environmental report need not contain information or analyses submitted to the Commission in the early site permit environmental report or resolved in the Commission's early site permit environmental impact statement, but must contain, in addition to the environmental information and analyses otherwise required: (1) Information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit; (2) information to resolve any significant environmental issue that was not resolved in the early site permit proceeding; (3) any new and significant information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding; (4) a description of the process used to identify new and significant information regarding the NRC's conclusions in the early site permit environmental impact statement, including a requirement that the process use a reasonable

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methodology for identifying such new and significant information; and (5) a demonstration that all environmental terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the combined license. Any terms or conditions of the early site permit that cannot be met by the time the combined license is issued must be set forth as terms or conditions of the combined license.

For an early site permit, the NRC prepares an EIS that resolves numerous issues within certain bounding conditions. These issues have issue preclusion at the combined license or CP stage provided certain conditions are met. A combined license or CP application must demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit. In addition, the application must include any new and significant information for issues related to the impacts of construction and operation of the facility (i.e., the issue being addressed at the combined license stage) that were resolved in the early site permit proceeding. Documentation related to the applicant's search for new information and its determination about the significance of the new information should be maintained in an auditable form by the applicant. The NRC staff may also use the environmental scoping process to assist it in determining if there is new and significant information regarding issues that were resolved in the early site permit proceeding. Although the NRC is ultimately responsible for completing any required NEPA review under 10 CFR 51.70(b), for example, an evaluation of the impact of new and significant information on the conclusions for a resolved early site permit environmental issue, the combined license applicant must identify whether there is new and significant information on such an issue. A combined license applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form. The NRC staff will verify that the applicant's process for identifying new and significant information is effective.

The NRC, in the context of a combined license application that references an early site permit, has defined the term "new" in the phrase "new and significant information" as any information that was both (1) not considered in preparing the ESP environmental report or EIS (as may be evidenced by references in these documents, applicant responses to NRC requests for additional information, comment letters, etc.) and (2) not generally known or publicly available during the preparation of the EIS (such as information in reports, studies, and treatises). For new information to be "significant," it must be material to the issue being considered, that is, it must have the potential to affect the finding or conclusions of the NRC staff's evaluation of the issue. The COL applicant need only provide information about a previously resolved environmental issue if it is both new and significant.

The combined license applicant referencing an early site permit is also required to provide information sufficient to resolve any other significant environmental issue not considered in the early site permit proceeding (e.g., need for power) and the information contained in the application should be sufficient to aid the staff in its development of an independent analysis (see 10 CFR 51.45).

Finally, the combined license applicant referencing an early site permit must demonstrate that all environmental terms and conditions included in the early site permit will be satisfied by the date of issuance of the combined license. In some cases, this may require adding a condition to the combined license to adequately address the environmental issue raised in the early site permit condition. Note that this provision was added to § 51.50(c)(1) in the final rule. Requirements to include environmental conditions in an early site permit environmental report were addressed in the proposed rule in § 51.50(b), but the associated provision to ensure any conditions included in the permit would be met was inadvertently left out of § 51.50(c)(1).

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

For license renewal, the NRC prepared a generic EIS (GEIS) that resolved more than 60 issues for all plants based on certain bounding assumptions. These were termed Category 1 issues. If a license renewal applicant identifies new and significant information with respect to a Category 1 issue, it documents its assessment of that information in its application. If the applicant determines that this new information is not significant, or that there is no new information, the applicant documents the bases for these determinations in an auditable form and makes the documentation available for staff inspection. If there is new and significant information on a Category 1 issue, the NRC staff limits its inquiry to determine if this information changes the Commission's earlier conclusion set forth in the GEIS. The NRC staff may inquire if the applicant has a reasonable process for identifying new and significant information on Category 1 issues.

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

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

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

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will not be subject to litigation at the combined license stage.

9. Section 51.51, Uranium Fuel Cycle Environmental Data—Table S–3

The NRC is revising § 51.51 to require that every environmental report prepared for the early site permit stage or combined license stage of a light-water-cooled nuclear power reactor use Table S–3, Table of Uranium Fuel Cycle Environmental Data, as the basis for evaluating the contribution of the environmental effects of the uranium fuel cycle to the environmental costs of licensing light-water-cooled nuclear power reactors. If the application for a combined license references an early site permit in which the environmental impacts and costs related to the uranium fuel cycle were already evaluated and resolved, then the repetition of this information in the environment report for the combined license is not required unless the applicant has identified new and significant information regarding these environmental impacts and costs.

10. Section 51.52, Environmental Effects of Transportation of Fuel and Waste—Table S–4

The NRC is revising § 51.52 to require that every environmental report prepared for the early site permit stage or combined license stage of a light-water-cooled nuclear power reactor contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. If the application for a combined license references an early site permit in which the transportation of fuel and radioactive wastes to and from the reactor has already been evaluated and resolved, then the repetition of this information in the environment report for the combined license is not necessary unless the applicant has identified new and significant information regarding the associated environmental impacts.

11. Section 51.53, Postconstruction Environmental Reports

The NRC is revising § 51.53(a) to clarify that any postconstruction environmental report may incorporate by reference any information contained in a prior environmental report or supplement thereto that relates to the site or any information contained in a final environmental document previously prepared by the NRC staff that relates to the site. This change reflects the recognition that environmental documents will be prepared at the early site permit stage and may be referenced in environmental documents for future licensing actions. The NRC is also revising § 51.53(a) to clarify that documents that may be referenced in post-construction environmental reports include those prepared in connection with an early site permit or a combined license. In addition, the NRC is revising § 51.53(c)(3) to clarify that the requirements for the content of environmental reports submitted in applications for renewal of a combined license are the same as those for renewal of an operating license.

12. Section 51.54, Environmental Report—Manufacturing License

The NRC is revising this section by adding two paragraphs to delineate the difference in the matters with respect to SAMDAs that must be addressed in an environmental report for issuance of a manufacturing license under subpart F of part 52, versus that for an amendment to the manufacturing license. Section 51.54(a) provides that the environmental report for the manufacturing license must address the costs and benefits of SAMDAs, and the bases for not incorporating into the design of the manufactured reactor any SAMDAs identified during the applicant's review. Section 51.54(b) reflects the narrower scope of an 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.

13. Section 51.55, Environmental Report—Standard Design Certification

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

14. Section 51.58, Environmental Report—Number of Copies; Distribution

The matters previously addressed in § 51.55 are addressed in a new § 51.58. The NRC is adding conforming references to § 51.58(a) for early site permits and combined licenses. Section 51.58(b) contains a conforming reference to subpart F of part 52.

15. Section 51.71, Draft Environmental Impact Statement—Contents

The NRC is revising § 51.71(d) to include a reference to § 51.75 in the first sentence because § 51.75 also includes exceptions to the provisions in § 51.71(d). This represents a change the NRC is making in the final rule to move the specific discussions on early site permits and combined licenses from § 51.71(d) to their associated paragraphs in § 51.75. The NRC is also revising associated footnote 3 to include references to early site permits and combined licenses.

16. Section 51.75, Draft Environmental Impact Statement—Construction Permit, Early Site Permit, or Combined License

The NRC is adding §§ 51.75(b) and (c) to include separate requirements for the preparation of draft EISs at the early site permit and combined license stages. In the final rule, the NRC is also moving information related to early site permits that was contained in proposed § 51.71(d) to § 51.75(b). In addition, the NRC is providing further clarification in the final rule on the scope of the environmental review at the early site permit stage. Section 51.75 requires that the draft environmental impact statement must include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed. The draft environmental impact statement must also include an evaluation of the environmental effects of construction

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and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, but only to the extent addressed in the early site permit environmental report or otherwise necessary to determine whether there is any obviously superior alternative to the site proposed. The purpose of this change is to clearly delineate that the scope of the environmental review at the early site permit stage is, at a minimum, to address all issues needed for the NRC to perform its evaluation of the alternative sites. In addition, the applicant may choose to address one or more issues related to construction and operation of the facility with the goal of achieving finality on those issues at the early site permit stage. The NRC also notes that, where the early site permit application identifies a specific nuclear power reactor design (i.e., a standard design certification or manufacturing license) under § 52.17(a)(1)(i), the environmental report for an early site permit may address the applicability of the severe accident mitigation design alternatives (SAMDA) evaluation for that reactor design to the proposed site. In this situation, the early site permit EIS must determine whether the site characteristics bound the site parameters relevant to the SAMDA analysis, as specified in the environmental assessment for the identified nuclear power reactor design.

The requirements for combined licenses are organized into separate paragraphs (c)(1), (c)(2), and (c)(3) which address the contents of the combined license environmental impact statement if the combined license application references an early site permit or standard design certification, or proposes to use a manufactured reactor. For example, § 51.75(c)(3) provides that the combined license EIS will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

In the final rule, § 51.75(c)(1) states that if a combined license application references an early site permit, then the NRC staff shall prepare a supplement to the early site permit EIS. Paragraph (c)(1) also requires that the supplement be prepared in accordance with § 51.92. Section 51.92 contains the requirements for the content of a supplemental EIS prepared for a combined license application that references an early site permit.

17. Section 51.92, Supplement to the Final Environmental Impact Statement

The NRC is revising § 51.92 in the final rule to provide requirements for NRC staff preparation of a supplement to the final environmental impact statement for an early site permit as required by § 51.75(c)(1). Paragraph (b) of § 51.92 states that, in a proceeding for a combined license application referencing an early site permit, the NRC staff shall prepare a supplement to the final environmental impact statement for the referenced early site permit in accordance with § 51.92(e). In the final rule, the NRC is moving information related to combined licenses that was contained in proposed § 51.71(d) to § 51.92(e) and is revising the wording of this provision. In the proposed rule, § 51.71(d) stated that the draft supplemental environmental impact statement prepared at the combined license stage when an early site permit is referenced need not include detailed information or analyses that were resolved in the final environmental impact statement prepared by the Commission in connection with the early site permit, provided that the design of the facility falls within the design parameters specified in the early site permit, the site falls within the site characteristics specified within the early site permit, and there is no new and significant environmental issue or information not considered on the site or the design only to the extent that they differ from that discussed in the final environmental impact statement prepared by the Commission in connection with the early site permit. In the final rule, the NRC has modified these provisions and moved them to § 51.92(e). The revised language in paragraph (e) provides a clearer link to the finality provisions in § 52.39, eliminates language in the proposed rule that attempted to define "new and significant," and provides greater consistency with related requirements elsewhere in part 51. Specifically, paragraph (e) requires that a supplement to an early site permit final environmental impact statement must: (1) Identify the proposed action as the issuance of a combined license for the construction and operation of a nuclear power plant as described in the combined license application at the site described in the early site permit referenced in the combined license application; (2) incorporate by reference the final environmental impact statement prepared for the early site permit; (3) contain no separate discussion of alternative sites; (4) include an analysis of the economic, technical, and other benefits and costs of the proposed action, to the extent that the final environmental impact statement prepared for the early site permit did not include an assessment of these benefits and costs; (5) include an analysis of other energy alternatives, to the extent that the final environmental impact statement prepared for the early site permit did not include an assessment of energy alternatives; (6) include an analysis of any environmental issue related to the impacts of construction or operation of the facility that was not resolved in the proceeding on the early site permit; and (7) include an analysis of the issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding for which new and significant information has been identified, including, but not limited to, new and significant information demonstrating that the design of the facility falls outside the site characteristics and design parameters specified in the early site permit.

18. Section 51.95, Postconstruction Environmental Impact Statements

The NRC is revising § 51.95(a) to indicate that documents that may be referenced in a supplement to a final environmental impact statement include documents prepared in connection with an early site permit or combined license. In addition, the NRC is revising § 51.95(c) to add provisions for renewal of combined licenses and to correct the address for the NRC Public Document Room. The NRC is revising § 51.95 to indicate that the NRC will prepare a supplemental environmental impact statement in connection with the amendment of a combined license authorizing decommissioning activities or with the issuance, amendment, or renewal of a license to store spent fuel at a nuclear power reactor after expiration of the combined license, and that the supplement may incorporate by reference any information contained in the final environmental impact statement for the combined license or in the records of decision prepared in accordance with an early site permit or combined license. Finally, the NRC is revising § 51.95(d) to indicate that, unless otherwise required by the Commission, in accordance with the provisions of § 51.23(b), a supplemental environmental impact statement for the post combined license stage will address the environmental impacts of spent fuel storage only for the term of the license, amendment, or renewal applied for.

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19. Section 51.105, Public Hearings in Proceedings for Issuance of Construction Permits or Early Site Permits

The NRC is revising the section heading and § 51.105(a) to indicate that the requirements for presiding officers in public hearings on construction permits also apply to public hearings on early site permits. In addition, the NRC is adding § 51.105(b) to indicate that the presiding officer in an early site permit hearing shall not admit contentions concerning the benefits assessment (e.g., need for power), or alternative energy sources if the applicant did not address those issues in the early site permit application. This change is being made for consistency with the provisions of § 51.50(b), which state that an environmental report included in an early site permit application need not include an assessment of the benefits (e.g., need for power) of the proposed action, and with the Commission's denial of a Petition for Rulemaking (See PRM–52–02 (October 28, 2003; 68 FR 55905)). The NRC notes that the environmental report and EIS for an early site permit must address the benefits associated with issuance of the early site permit (e.g., early resolution of siting issues, early resolution of issues on the environmental impacts of construction and operation of a reactor(s) that fall within the site characteristics, and ability of potential nuclear power plant licensees to "bank" sites on which nuclear power plants could be located without obtaining a full construction permit or combined license). The benefits (and impacts) of issuing an early site permit must always be addressed in the environmental report and EIS for an early site permit, regardless of whether the early site permit applicant chooses to defer consideration of the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site. This is because the "benefits * * * of the proposed action" for which the discussion may be deferred are the benefits associated with the construction and operation of a nuclear power plant that may be located at the early site permit site; the benefits which may be deferred are entirely separate from the benefits of issuing an early site permit. The presiding officer needs to be mindful of whether the applicant has addressed only the benefits of issuing the early site permit or whether the applicant has also addressed all of the benefits of construction and operation of the facility. This is because the presiding officer, in accordance with § 51.105(a)(3), must determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the early site permit should be issued, denied, or appropriately conditioned to protect environmental values. If the applicant has addressed all of the costs and benefits associated with construction and operation of the facility in its environmental report, the final balancing between costs and benefits needs to occur at the early site permit stage.

The NRC also notes that, where the early site permit application identifies a specific nuclear power reactor design (i.e., a standard design certification or manufacturing license) under § 52.17(a)(1)(i), the environmental report for an early site permit may address the applicability of the severe accident mitigation design alternatives evaluation for that reactor design to the proposed site. In this situation, the early site permit EIS must determine whether the site characteristics bound the site parameters relevant to the SAMDA analysis, as specified in the environmental assessment for the identified nuclear power reactor design. In addition, in accordance with Section 52.107(c), the presiding officer shall not admit contentions proffered by any party concerning severe accident mitigation design alternatives unless the contention demonstrates that the site characteristics fall outside of the site parameters in the standard design certification or underlying manufacturing license for the manufactured reactor.

20. Section 51.105a, Public Hearings in Proceedings for Issuance of Manufacturing Licenses

The NRC is adding § 51.105a to provide requirements for public hearings in proceedings for issuance of manufacturing licenses. Specifically, § 51.105a establishes that the presiding officer in a proceeding for a manufacturing license will determine whether the manufacturing license should be issued as proposed by the appropriate NRC staff director.

21. Section 51.107, Public Hearings in Proceedings for Issuance of Combined Licenses

The NRC is adding § 51.107 to set out the requirements for public hearings in proceedings for issuance of combined licenses. The requirements parallel the associated requirements for public hearings on construction permits and operating licenses, as appropriate, and provide requirements unique to the combined license process that are derived from various provisions in part 52, namely §§ 52.39 and 52.103. The NRC is making changes to the language in § 51.107 in the final rule to more clearly define the role of the presiding officer in a proceeding for the issuance of a combined license where an early site permit is being referenced. Specifically, paragraph (b) addresses the situation where a combined license application references an early site permit and a supplement to the early site permit environmental impact statement is prepared in accordance with § 51.75(c)(1) and § 51.92(e). In such cases, the presiding officer in the combined license hearing shall not admit any contention proffered by any party on environmental issues which have been accorded finality under § 52.39 unless the contention: (1) Demonstrates that the nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit; (2) raises any significant environmental issue that was not resolved in the early site permit proceeding; or (3) raises any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which new and significant information has been identified.

N. Changes to 10 CFR Part 54

1. Section 54.1, Purpose

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

2. Section 54.3, Definitions

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

3. Section 54.17, Filing of Application

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

4. Section 54.27, Hearings

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

5. Section 54.31, Issuance of a Renewed License

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

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6. Section 54.35, Requirements During Term of Renewed License

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

7. Section 54.37, Additional Records and Recordkeeping Requirements

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

O. Changes to 10 CFR Part 55

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

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

P. Changes to 10 CFR Part 72

1. Section 72.210, General License Issued

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

2. Section 72.218, Termination of Licenses

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

Q. Changes to 10 CFR Part 73

Part 73 establishes the NRC's requirements for the physical protection of production and utilization facilities licensed by the NRC. It provides requirements for the physical protection of licensed activities, for personnel access authorization, and for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information. Formerly, the language of § 73.1, *Purpose and scope,* § 73.2, *Definitions,* § 73.50, *Requirements for physical protection of licensed activities,* § 73.56, *Personnel access authorization requirements for nuclear power plants,* and § 73.57, *Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to Safeguards Information by power reactor licensees,* and Appendix C, *Licensee Safeguards Contingency Plans,* did not refer to combined licenses issued under part 52. However, part 73 was formerly applicable to combined licenses under the provisions of § 52.83, *Applicability of part 50 provisions,* which states that all provisions of 10 CFR part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses. Accordingly, § 73.1 is revised to clarify that the regulations in part 73 apply to persons who receive combined licenses under part 52, and § 73.2 is revised to state that terms defined in part 52 have the same meaning when used in part 73. The NRC has addressed combined licenses in § 73.57 by making the provisions that are required before receiving an operating license under part 50 applicable before the date that the Commission makes the finding under § 52.103 for a combined license. Additional conforming changes to include part 52 licenses are made for §§ 73.50 and 73.56, and appendix C to part 73.

R. Change to 10 CFR Part 75

1. Section 75.6, Maintenance of Records and Delivery of Information, Reports, and Other Communications

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

S. Changes to 10 CFR Part 95

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

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

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

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license, certificate, or standard design approval or standard design certification under part 52."

T. Changes to 10 CFR Part 140

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

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

U. Changes to 10 CFR Part 170

Part 170 sets out the fees charged for licensing services performed by the NRC. The NRC is revising § 170.2(g) and (k) to add conforming references to manufacturing licenses and standard design approvals issued under part 52, revise the existing reference to appendix Q to part 52 to be a reference to appendix Q to part 50, and delete the reference to a manufacturing license issued under part 50 (which is being removed from part 50 because of its transfer to part 52 in the 1989 rulemaking adopting part 52).

V. Changes to 10 CFR Part 171

Part 171 sets out the annual fees charged to persons who hold licenses issued by the NRC. The NRC is revising § 171.15 to add conforming references to combined licenses issued under part 52. Note that for combined licenses, the requirements of part 171 are not applicable until after the Commission has made the finding under § 52.103(g). This section also provides fee requirements for each person holding a part 50 power reactor license that is in decommissioning or possession only status and each person holding a part 72 license who does not hold a part 50 license. The NRC also added conforming changes to include references in part 52 in these provisions.

VI. Section-by-Section Analysis

Part 52, General Provisions

Section 52.0 Scope; Applicability of 10 CFR Chapter I Provisions

This section, formerly designated as § 52.1, has been expanded to: (1) address all licensing and regulatory processes covered in part 52; and (2) more clearly define the relationship between part 52 and remaining provisions of 10 CFR Chapter I. Paragraph (a), which establishes the scope of part 52, is revised by referring to all licensing and regulatory processes covered in part 52. In addition, paragraph (a) is revised to give notice to contractors, subcontractors or consultants of applicants for or holders of licenses or regulatory approvals under part 52 that they are subject to NRC enforcement action for violations of the deliberate misconduct proscriptions in § 52.4. The Commission notes, as discussed below in the section-by-section analysis of § 52.4, that deliberate misconduct under § 52.4 may occur as the result of a violation of any Commission rule and regulation throughout 10 CFR Chapter I, not just a violation of a requirement in part 52.

Paragraph (b) is a new provision that supersedes former § 52.83. The first sentence of paragraph (b) is intended to make clear that the Commission's regulations in 10 CFR Chapter I apply to applicants and holders of licenses, permits and other regulatory approvals in part 52 (e.g., design approvals and standard design certifications). Accordingly, applicants, licensees and holders of regulatory approvals under part 52 should review the regulations in 10 CFR Chapter I to ensure that they are in compliance with applicable Commission requirements throughout 10 CFR Chapter I. The second sentence of paragraph (b) reinforces the applicability of the Commission's requirements throughout 10 CFR Chapter I to part 52 licenses, permits, and other regulatory approvals. As part of this final rule, the Commission is making conforming changes as necessary throughout Chapter I to ensure that relevant regulations clearly set forth their applicability to part 52 licenses and approvals, and to part 52 entities such as applicants, licensees, and holders. Nonetheless, the Commission is adopting paragraph (b) in order to clearly and unambiguously impose applicable regulatory requirements that exist throughout 10 CFR Chapter I.

Section 52.1 Definitions

This section, formerly designated as § 52.2, has been supplemented by: (1) adding definitions of terms that are used in part 52 but were undefined in the previous rule; and (2) providing definitions of new terms that were added in this rulemaking to provide greater clarity and precision. New definitions which are noteworthy are discussed individually as follows.

A definition of *modular design* is added to explain the type of modular reactor design to which the Commission intended to refer to in the second sentence of the current § 52.103(g). This special provision for modular designs was added to part 52 to facilitate the licensing of nuclear plants, such as the Modular High Temperature Gas-Cooled Reactor (MHTGR) and Power Reactor Innovative Small Module (PRISM) designs, that consisted of three or four nuclear reactors in a single power block with a shared power conversion system. During the period that the power block is under construction, the Commission could separately authorize operation for each nuclear reactor when each reactor and all of its necessary support systems were completed. The Commission believes that the term "modular design" needs to be defined to aid future use of the current § 52.103(g) by distinguishing the intended definition from other currently used definitions for "modular design." Also, future combined license applicants for a multi-unit site that would be similar to current multi-unit sites (where each unit is similar in design but independent of all other units) could use this provision.

Definitions of the terms *design characteristics, design parameters, site characteristics,* and *site parameters* were added to § 52.1 to clarify their meaning and use in the licensing and approval processes of part 52. *Design characteristics* are defined as the actual features of a nuclear reactor or reactors. Design characteristics are specified in the final safety analysis report for a standard design approval, a standard design certification, a combined license application, or a manufacturing license. *Design parameters* are defined as the postulated features of a nuclear reactor or reactors that could be built at the proposed site. Design parameters are specified in an early site permit application. *Site characteristics* are defined as the actual physical, environmental, and demographic

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features of a site. Site characteristics are specified in an early site permit or combined license application. *Site parameters* are defined as the postulated physical, environmental, and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or manufacturing license.

The values for the characteristics and parameters will be used in the NRC's review of combined license applications that reference design approvals, design certifications, manufacturing licenses, or early site permits. For example, § 52.79(b) requires that a combined license application referencing an early site permit contain information sufficient to demonstrate that the actual design characteristics of the nuclear facility fall within the design parameters and site characteristics specified in the early site permit. Also, § 52.79(d) requires that a combined license application referencing a design certification rule must contain information sufficient to demonstrate that the actual site characteristics fall within the site parameters specified in the design certification.

The above terms are also used in §§ 52.39 and 52.93. Because the NRC is relying on certain design parameters specified in the early site permit applications to reach its conclusions on site suitability, these design parameters will be included in any early site permit issued. The NRC believes that its review of a combined license application that references an early site permit will involve a comparison to ensure that the actual characteristics of the design chosen by the combined license applicant fall within the design parameters specified in the early site permit. A combined license application that references a design certification will involve a comparison to ensure that the actual characteristics of the site chosen by the combined license applicant fall within the site parameters in the design certification. Similarly, if a combined license applicant references both an early site permit and a design certification, the NRC will review the application to ensure that the site characteristics in the early site permit fall within the site parameters in the referenced design certification and that the actual design characteristics fall within the design parameters in the early site permit.

A new definition of *major features of the emergency plans* is added to explain what aspects of emergency preparedness—short of full and integrated emergency plans—an early site permit applicant may seek approval of under § 52.17(b)(2)(i). A major feature may consist of a specific aspect of a plan necessary to address in whole or part 1 or more of the 16 planning standards in 10 CFR 50.47(b). Additional requirements for each of the planning standards are set forth in part 50, appendix E, and the applicant may choose to demonstrate compliance with one or more provisions in appendix E, either in addition to or without a full demonstration of compliance with a planning standard in § 50.47(b), when seeking approval of part of a major feature. A major feature may also be a description of one or both of the emergency planning zones (EPZs) required by 10 CFR 50.33(g). Regulatory considerations governing EPZs are set forth in § 50.33(g); a major feature need not address all of these considerations.

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

Section 52.2 Interpretations

This section, formerly designated as § 52.5, remains unchanged. It provides that the only interpretations of part 52 that are legally binding on the Commission are interpretations provided by the General Counsel. These written interpretations, which are rarely provided by the General Counsel, are set forth in 10 CFR part 8.

Section 52.3 Written Communications

This new section, which is analogous to § 50.4, sets forth administrative requirements regarding written communications with the NRC, including the addressing of such communications, and listings of the various NRC offices and officials who must receive copies of different types of communications (e.g., applications for licenses and license amendments, security plan and related submissions, quality assurance related submissions). The administrative requirements themselves are identical to those in § 50.4; they are reproduced in § 52.3 to make clear that they apply to applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52.

Section 52.4 Deliberate Misconduct

This section, formerly designated as § 52.9, has been substantially rewritten in order to more clearly delineate the applicability of the proscriptions against deliberate misconduct to all delineated part 52 entities, including applicants for and holders of standard design approvals, and applicants for standard design certifications (including those applicants whose designs are certified by the Commission in a standard design certification rulemaking). Although the regulatory language in § 52.4 differs from former § 52.9, no substantive change in any aspect of the Commission law or the underlying policy considerations is being made by the Commission's adoption of § 52.4. The relevant law and policy considerations for former § 52.9 are merely clarified and extended in § 52.4 to cover applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52.

Section 52.5 Employee Protection

This new section, which is analogous to § 50.7, prohibits discrimination against employees for engaging in protected activities established in Section 211 of the Energy Reorganization Act of 1974, as amended (1974 ERA). These protected activities, which are listed in § 52.5(a)(1), include (but are not limited to) providing the Commission or the employer information about alleged violations of the AEA or 1974 ERA, of any of the Commission's regulations. No substantive change in any aspect of the Commission law or the underlying policy considerations with respect to employee protection is being made by the Commission adoption of § 52.5; the relevant law and policy considerations for former § 50.7 are merely clarified and extended in § 52.5 to cover applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52 (currently, standard design approvals and standard design certifications).

Section 52.6 Completeness and Accuracy of Information

This new section, which is analogous to § 50.9, requires that all information submitted to the NRC by the delineated part 52 entities be complete and accurate, and imposes a reporting requirement on such entities with respect to information with respect to the regulated activity having a significant implication for public health and safety or common defense and security. No substantive change in any aspect of the Commission law or the

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underlying policy considerations is being made by the Commission adoption of § 52.6; the relevant law and policy considerations underlying § 50.9 are merely clarified and extended to cover applicants for and holders of permits, licenses and regulatory processes that are contained in part 52. For example, § 50.9 does not impose a positive obligation on licensees to seek out new information meeting the reporting thresholds in the rule. In applying § 52.6, the Commission would extend this interpretation to part 52 entities such as combined license holders and standard design certification applicants (including applicants whose applications were approved, for the regulatory life of the certification rule).

Section 52.7 Specific Exemptions

This new section, which is analogous to § 50.12, provides for specific procedures and criteria for Commission grants of exemptions from the provisions of part 52. No substantive change in any aspect of the Commission law or the underlying policy considerations is being made by the Commission adoption of § 52.7; the relevant law and policy considerations underlying § 50.12 are merely extended to part 52.

The NRC notes that the exemption provisions in § 52.7 do not supercede or otherwise diminish more specific exemption provisions that are in part 52, such as the provision of a specific design certification rule or § 52.63(b)(1) governing exemptions from one or more elements of a design certification rule. An applicant or licensee referencing a standard design certification rule who wishes to obtain an exemption from one or more elements must meet the criteria in the specific design certification rule or § 52.63(b)(1). If the applicant or licensee is unable to demonstrate compliance with those criteria, then it may request an exemption under the more encompassing authority of § 52.7. However, the exemption request must then demonstrate compliance with the additional criteria in § 52.7.

The Commission also notes that § 52.7 does not supercede the applicability of more specific dispensation provisions in other parts of Chapter I. For example, a holder of a combined license would not require a separate part 52 exemption in order to obtain approval of an alternative to a provision of an applicable ASME Code provision that is otherwise required under 10 CFR 50.55a; the licensee need only satisfy the criteria in § 50.55a(a)(3). However, in the absence of a more specific dispensation provision, the Commission intends to utilize § 52.7 as a means for granting dispensation from compliance with Commission requirements in other parts of 10 CFR Chapter I. The person requesting an exemption need only address the § 52.7 criteria as applied to the underlying requirement for which dispensation from compliance is sought, and need not also address dispensation from compliance with the relevant part 52 requirement. For example, the holder of the combined license who wishes dispensation from compliance with a fire protection requirement in 10 CFR 50.48 need only address the relevant criteria in § 52.7 with respect to the reasons for dispensation from compliance with § 50.48. The holder need not address dispensation from compliance with § 52.0, which otherwise makes applicable the provisions of § 50.48 on the licensee. Any exemption granted by the Commission would address the reasons for dispensation with the underlying requirement—in this case, § 50.48, and would also provide dispensation from compliance with § 52.0.

Section 52.8 Combining Licenses; Elimination of Repetition

This new section includes provisions analogous to §§ 50.31, 50.32, and 50.52 and is added to clarify that these regulatory provisions also apply to part 52 licenses. Paragraph (a), which is analogous to § 50.31, is added to make clear that an applicant for a license under part 52 may combine in one application, several applications for different kinds of licenses under various regulations in 10 CFR Chapter I. Section 50.31 currently provides that an applicant may combine in one application, several applications for different kinds of licenses under various regulations in 10 CFR Chapter I. The plain reading of this language, given that this provision is located in part 50, is that a part 50 application may contain in one application other applications for different licenses in other parts of 10 CFR Chapter I. Thus, § 50.31 would not appear to allow a part 52 application (as for a combined license) to combine in one application other applications for different license in other parts of 10 CFR Chapter I. Accordingly, paragraph (a) makes clear that a part 52 application may be combined with application for different licenses in other parts of 10 CFR Chapter I.

Paragraph (b), which is analogous to § 50.32, is added to make clear that an applicant for a license, standard design certification, or design approval under part 52 may incorporate by reference in its application information contained in other documents provided to the Commission, but that such incorporation must clearly specify the information to be incorporated.

Paragraph (c), which is analogous to § 50.52, is added to clarify the Commission's authority under Section 161.h of the AEA to combine NRC licenses, such as a special nuclear materials license under part 70 for the reactor fuel, with a combined license under part 52. Analogous to the situation with respect to § 50.31, the language in § 50.52 would not appear to allow the Commission to combine into a single part 52 license, other non-part 52 licenses. No substantive change in any aspect of the Commission law or the policy considerations underlying §§ 50.31, 50.32, and 50.52 is being made by the Commission adoption of § 52.8; the relevant law and policy considerations underlying §§ 50.31, 50.32, and 50.52 are merely extended to part 52.

Section 52.9 Jurisdictional Limits

This new section, which is analogous to § 50.53, makes clear that no approval provided by the Commission under part 52 addresses or approves in any manner activities which are not under or within the territorial jurisdiction of the United States. As a practical matter, this means that an approval or license issued by the NRC under part 52 has no legal effect outside the territorial jurisdiction of the United States. No substantive change in any aspect of the Commission law or the policy considerations underlying § 50.53 is being made by the Commission adoption of § 52.9; the relevant law and policy considerations are merely extended to part 52.

Section 52.10 Attacks and Destructive Acts

This new section, which is analogous to § 50.13, applies the existing Commission law and policy that a licensee need not provide for design features or other measures to protect against certain attacks and destructive acts, or the use or deployment of weapons incident to U.S. defense activities, to the applicants for and holders of permits, licenses and other approvals under part 52. No substantive change in any aspect of the Commission law or the underlying policy considerations is being made by the Commission adoption of § 52.10; the relevant law and policy considerations for the § 50.13 exclusion are merely extended to cover applicants for and holders of permits, licenses, and regulatory processes that are contained in part 52.

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Section 52.11 Information Collection Requirements: OMB Approval

This section, formerly designated as § 52.8, remains unchanged. It gives notice that all information collection and reporting requirements in part 52 have been approved by the Office of Management and Budget. No requirement, action or responsibility is imposed on part 52 entities by this section.

Subpart A—Early Site Permits

Section 52.12 Scope of Subpart

This section describes the scope of this licensing process. Under this subpart an applicant can request pre-approval of a site (so-called site banking), separate from other licensing actions, and subsequently reference that early site permit in a future application to build a nuclear power plant. This process was created for proposed sites that the applicant may not plan to use in the near term.

Section 52.13 Relationship to Other Subparts

This section explains the relationship of the early site permit process to the construction permit process under 10 CFR part 50 and to the combined license process under part 52.

Section 52.15 Filing of Applications

This section explains who can file, how to file, and the fees for NRC review of an application for an early site permit.

Section 52.16 Contents of Applications; General Information

This section sets forth the type of general information that is required to be included in an early site permit application, namely, the information required by 10 CFR 50.33(a) through (d) and (j). Section 50.33 requires that the application include information such as the name and address of the applicant, a description of the business or occupation of the applicant, and citizenship information of the applicant. Section 50.33 also provides requirements for the handling of Restricted Data or other defense information in an application.

Section 52.17 Contents of Applications; Technical Information

The purpose of this section is to set forth the type of technical information to be included in an application for an early site permit. Paragraph (a)(1) identifies the information needed for the site safety review, excluding emergency planning information. The site safety information is a subset of the information required of applicants for construction permits. Although an ESP applicant does not need to specify a particular nuclear plant design, as in construction permit applications, it does need to provide sufficient surrogate design information (developed to bound the nuclear plant design(s) that are being considered by the applicant) so that the NRC can make a determination on the acceptability of the site and the environmental impacts, and determine whether designs bounded by the surrogate design information provided by the applicant can be qualified for the proposed site. The application must contain, among other things, the specific number, type (e.g., pressurized-water reactor), and thermal power level of the facilities, or range of possible facilities, for which the site may be used; the anticipated maximum levels of radiological and thermal effluents each facility will produce; the type of cooling systems, intakes, and outflows that may be associated with each facility; the boundaries of the site; and the proposed general location of each facility on the site. As part of the description of the proposed general location of each facility on the site (§ 52.17(a)(1)(v)), the applicant should describe the foot print for all structures and external safety-related design features proposed for the site.

The application must also include the seismic, meteorological, hydrologic, and geologic characteristics of the proposed site with appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area and with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated. This information is to ensure that future plants built at the site would be in compliance with General Design Criterion 2 from appendix A to part 50, which requires that structures, systems, and components important to safety be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions.

The application must also include the location and description of any nearby industrial, military, or transportation facilities and routes, and the existing and projected future population profile of the area surrounding the site. The application must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site from a radiological safety standpoint. In addition, the application must demonstrate that adequate security plans and measures can be developed for the site and must provide a description of the quality assurance program applied to site-related activities.

Paragraph (a)(2) identifies that the application must include an environmental report that meets the requirements of § 51.50(b). Environmental reports must focus on the environmental effects of construction and operation of a nuclear reactor, or reactors, which have characteristics that fall within the design parameters postulated in the early site permit. Environmental reports must also include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed. Environmental reports submitted in an early site permit application are not required to but may include an assessment of the economic, technical, and other benefits and costs of the proposed action or an analysis of other energy alternatives.

Paragraph (b) identifies the emergency planning information to be included in the application. All ESP applicants are required to identify in the site safety analysis report (SSAR) physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans, e.g., a physical characteristic or combination of physical characteristics that could pose major difficulties for evacuation or the taking of other protective actions. In addition, if the applicant identifies such physical characteristics, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. After meeting this mandatory requirement, paragraph (b) allows applicants the option of either submitting major features of emergency plans or complete and integrated emergency plans for approval by the NRC, in consultation with the Department of Homeland Security (DHS). For complete and integrated emergency plans, the applicant must include the proposed inspections, tests, and analyses that the holder of a combined license referencing the early site permit shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act,

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and the NRC's regulations. The inclusion of such inspections, tests, analyses, and acceptance criteria (ITAAC) is necessary to allow the NRC to make the finding that the plans submitted by the applicant provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Paragraph (b) also allows applicants proposing major features of emergency plans to include proposed ITAAC. Where the applicant is submitting a complete and integrated emergency plan, a utility plan must be submitted if any offsite agencies elect not to participate in the development of emergency planning information.

If the applicant plans to perform the preparations for construction activities identified in 10 CFR 50.10(e)(1), then paragraph 52.17(c) requires the applicant to describe the activities it is requesting to perform and propose a redress plan that, if carried out, would achieve a "self-maintaining, environmentally stable, and aesthetically acceptable site" that conforms to local zoning laws. Redress plans are expected to be modeled on the redress requirements imposed on the Clinch River Breeder Reactor project (see In the Matter of the U.S. Department of Energy, et al., LBP–85–7, 21 NRC 507 (1985)). By containing a redress plan, the ESP will constitute assurance that, if site preparation activities are conducted but the site is never used for a nuclear power plant, the site will be returned to an acceptable and stable condition.

Section 52.18 Standards for Review of Applications

This section identifies the regulations that the NRC staff will use in performing its review of an application for an early site permit, including the standards that the NRC staff will use in performing its assessment of emergency preparedness information provided in the ESP application.

Section 52.21 Administrative Review of Applications; Hearings

This section identifies the procedural requirements that apply to the mandatory hearing for the early site permit licensing process. This section also clarifies that the applicant's environmental report is not required to but may include an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources. In addition, the presiding officer in an ESP hearing is prohibited from admitting contentions on these matters if those issues were not addressed in the early site permit application.

Section 52.23 Referral to the Advisory Committee on Reactor Safeguards (ACRS)

This section states that the ACRS will report on those portions of the application which concern safety which is the same role the ACRS had with respect to construction permits in the past.

Section 52.24 Issuance of Early Site Permit

The purpose of this section is to set forth the timing of issuance of an ESP and the findings that the Commission must make to issue the ESP, including that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public, that the applicant is technically qualified to engage in activities necessary to prepare the ESP application and any site preparation activities that the applicant is seeking approval to perform, and that the findings required by subpart A of 10 CFR part 51 regarding the NRC staff's assessment of the environmental impact have been made.

This section also requires that the early site permit specify the site characteristics, design parameters, and terms and conditions of the early site. Before issuance of either a construction permit or a combined license referencing an early site permit, the Commission must find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions that could not be met by the time of issuance of the construction permit or combined license must be set forth as terms or conditions of the construction permit or combined license. Finally, this section requires that the early site permit specify the site preparation activities under § 52.17(c) that the permit holder is authorized to perform.

Section 52.25 Extent of Activities Permitted

This section specifies that, if the construction preparation activities authorized by § 52.24(c) are performed and the site is not referenced in a application for a construction permit or a combined license while the permit remains valid, then the early site permit remains in effect for the purpose of site redress with the goal of achieving an environmentally stable and aesthetically acceptable site.

Section 52.27 Duration of Permit

The purpose of paragraph (a) of this section is to specify the duration of an early site permit. The applicant can request a duration of up to 20 years. Paragraph (b) describes the conditions under which an ESP can continue to be valid beyond its expiration date. Paragraph (c) allows an applicant for a construction permit or combined license, at its own risk, to reference an ESP that is under review by the NRC but not yet granted. Paragraph (d) explains that, upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license. By "subsumed" the NRC means that the information that was contained in the early site permit SSAR becomes part of the referencing combined license FSAR upon issuance of the combined licenses in the same manner as if the combined license applicant had not referenced an early site permit. The NRC is including the phrase "to the extent referenced," to indicate that it is not all of the information submitted in the early site permit application that is subsumed into the combined license, but, rather, only that information that is contained in the SSAR and identified by the applicant as being referenced in the combined license application. This subsumption of the early site permit into the referencing license affects the way changes to the early site permit information will be handled because it breaks the tie to the finality provisions in § 52.39. After issuance of the construction permit or combined license, § 52.39 no longer applies to the early site permit information and such information will be covered by the same finality provisions as the rest of the information in the FSAR (with the exception of any referenced design certification information), as outlined in § 52.98 (e.g., in accordance with §§ 50.54, 50.59, etc.).

Section 52.28 Transfer of Early Site Permit

This section specifies the requirements to be followed if a holder of an early site permit wants to transfer the ESP to another person or company.

Section 52.29 Application for Renewal

Paragraph (a) of this section explains the contents and timing of an application for renewal of an early site permit. Paragraph (b) sets forth the procedure for requesting a hearing on the application for renewal. Paragraph (c) explains that an ESP may remain in effect beyond its expiration under

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certain circumstances. Specifically, an ESP for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the permit. If an ESP is not renewed, it continues to be valid in any proceeding on an application for a construction permit or a combined license which references the ESP and was docketed prior to the expiration of the ESP. Finally, paragraph (d) identifies the responsibilities of the ACRS on an ESP renewal application.

Section 52.31 Criteria for Renewal

Paragraph (a) of this section sets forth the criteria for granting a renewal of an early site permit and provides that, if the NRC wants to impose new requirements, it must demonstrate that the new requirements meet the backfit standard from § 50.109. Paragraph (b) explains that even if an application for renewal of an ESP is denied by the NRC, the applicant can submit a new application for an ESP that corrects the problems with the application for renewal.

Section 52.33 Duration of Renewal

This section specifies the duration of a renewed early site permit. An ESP may, upon application, be extended for periods of up to 20 years beyond the previously approved duration, provided the criteria in § 52.31 are met.

Section 52.35 Use of Site for Other Purposes

The purpose of this section is to explain how the holder of an early site permit could use the site for other activities. An approved site may be used for purposes not related to the construction of a nuclear power facility, e.g., a fossil-fueled station or a park, provided that the Commission is informed of all significant non-nuclear uses prior to actual construction or site modification activities. A permit may be revoked if a non-nuclear use would interfere with a nuclear use, or would so alter the site that important assumptions underlying the issuance of the permit were called into question.

Section 52.39 Finality of Early Site Permit Determinations

This section specifies the special backfit requirements that apply to an early site permit. Paragraph (a) provides requirements regarding finality of ESP issues as they relate to the Commission. Paragraph (a)(1) states that, notwithstanding any provision in 10 CFR 50.109 (Backfitting), while an early site permit or renewed early site permit is in effect, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission meets one of four conditions. Those conditions are that the Commission either determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued; determines that a modification is necessary to assure adequate protection of the public health and safety or the common defense and security; determines that a modification is necessary based on an update under § 52.39(b); or issues a variance requested under § 52.39(d).

Paragraph (a)(2) addresses the finality of an early site permit for a license that references the early site permit and requires that the Commission treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in §§ 52.39(b), (c), and (d). This paragraph also addresses finality of changes to an early site permit approved emergency plan (or major features thereof).

Paragraph (b) requires a license applicant that references an ESP to update and correct the emergency preparedness information that was provided in the ESP and to discuss whether the new information materially changes the bases for compliance with the applicable NRC requirements. New information which materially changes the bases for compliance includes: (1) Information which substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, and (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness, in accordance with § 52.39(a)(1). New information which materially changes the Commission's determination of the matters in § 52.17(b), or results in modifications of existing terms and conditions by the NRC under § 52.39(a)(1) would be subject to litigation during the licensing proceedings in accordance with § 52.39(c).

Section 52.39(c) provides requirements for the submittal of contentions in a proceeding for the issuance of a license referencing an early site permit and for the filing of petitions requesting that an early site permit be modified, suspended, or revoked. Paragraph (c)(1) states that contentions on several matters may be litigated in the proceeding on a combined license that references an early site permit. Matters that may be litigated include contentions related to the following: (1) The nuclear power reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit; (2) one or more of the terms and conditions of the early site permit have not been met; (3) a variance requested under § 52.39(d) is unwarranted or should be modified; (4) new or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for Commission to modify or impose new terms and conditions related to emergency preparedness; or (5) any significant environmental issue that was not resolved in the early site permit proceeding, or any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified. An issue related to the impacts of construction and operation of the facility resolved in the early site permit proceeding is afforded finality at the combined license stage provided that there is no "new and significant" information on the issue. If an environmental issue was not resolved at the early site permit stage, either because information was not sufficient to resolve it or because the early site permit applicant was permitted to defer it (e.g., need for power analysis), then the combined license applicant would need to address the issue in its combined license application. The NRC, in the context of a combined license application that references an early site permit, has defined the term "new" in the phrase "new and significant information" as any information that was both (1) not considered in preparing the ESP environmental report or EIS (as may be evidenced by references in these documents, applicant responses to NRC requests for additional information, comment letters, etc.) and (2) not generally known or publicly available during the preparation of the EIS (such as information in reports, studies, and treatises). This new information may or may not be significant. For an issue to be significant, it must be material to the issue being considered, i.e., it must have the potential to affect the NRC staff's evaluation of the issue. The COL applicant need only provide information about a previously resolved

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environmental issue if it is both new and significant.

Paragraph (c)(2) allows any person to file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit be modified, or that the permit be suspended or revoked. The petition will be considered in accordance with § 2.206. Section 2.206 provides that any person may file a request to institute a proceeding to modify, suspend, or revoke a license, or for any other action as may be proper. Section 52.39(c)(2) addresses the Commission's required action on such a petition and states that construction under the construction permit or combined license will not be affected by the granting of the petition unless the Commission makes the order immediately effective.

Paragraph (d) provides that an applicant for a license or an amendment to such a license who has filed an application referencing an early site permit may request a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the SSAR. This paragraph also states that, once a construction permit or combined license referencing an early site permit is issued, a variance from the early site permit will not be granted for that construction permit or combined license. At that point, the early site permit is subsumed into the combined license and any request for a change to the terms or conditions of the combined license is a request for a license amendment that must be filed under the provisions of § 50.90.

The NRC is adding new paragraph (e) in the final rule in response to public comments expressing support for adding provisions to provide an early site permit holder with the option of requesting an amendment to the early site permit in order to resolve issues that were not addressed in the original early site permit review or to achieve finality on updated early site permit information. Paragraph (e) states that the holder of an early site permit may not make changes to the early site permit, including the SSAR, without prior Commission approval. The request for a change to the early site permit must be in the form of an application for a license amendment, and must meet the requirements of 10 CFR 50.90 and 50.92. The NRC considers an early site permit SSAR to be equivalent to a combined license FSAR; therefore, when an early site permit is amended, the SSAR must be revised consistent with the ESP amendments. In addition, the SSAR retains continuing viability for early site permits that are for multiple units after it is referenced in the first combined license. However, unlike an FSAR, there is no change process for the SSAR that does not require NRC review and approval.

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

Subpart B—Standard Design Certifications

Section 52.41 Scope of Subpart

This section describes the scope of this licensing process for certification of standard nuclear power plant designs. Under this subpart, an applicant may request pre-approval of either an evolutionary light-water or advanced nuclear power plant design, separate from a site review or other licensing action, and subsequently reference that certified design in an application to build a nuclear power plant. The requirements for the type of plant to be certified were moved from § 52.45 to this section. The scope of the standard plant design must be essentially complete as described in § 52.47(c).

Section 52.43 Relationship to Other Subparts

The purpose of this section is to explain the relationship of the design certification process to the processes set forth in subparts C, E, and F of 10 CFR part 52, which provide for combined licenses, standard design approvals, and manufacturing licenses. The requirement to hold a final design approval under former appendix O to part 52 as a prerequisite to design certification was deleted from § 52.45. However, applicants for design certification have the option of also applying for a standard design approval under subpart E. Also, applicants for a manufacturing license may reference a certified design.

Section 52.45 Filing of Applications

This revised section is similar to the "filing of applications" sections in subparts A and C of this part. This section explains how to file an application for design certification and how the fees for NRC's review of the application will be assessed. Because design certification is a rule and not a license, the applicant for design certification does not need to be a U.S. citizen or company (AEA, Section 103).

Section 52.46 Contents of Applications; General Information

This is a new section and it is similar to the "general information" sections in subparts A and C of this part. It identifies the general information that must be included in all applications.

Section 52.47 Contents of Applications; Technical Information

The purpose of this section is to identify the technical information that must be included in an application for design certification. This section was revised to provide a comprehensive list of requirements for a design certification application. Paragraphs (a) and (c) describe the information that must be included in the FSAR, which is included in the application, and paragraph (b) describes the information that must also be included in the application but does not need to be included in the FSAR. Paragraph (c) describes additional requirements for particular types of applications. This section also specifies the level of detail for the design information that must be provided in an application.

Many of the requirements in this section were taken from 10 CFR 50.34 or are pointers to technical requirements in parts 20, 50, 51, and 73 that must be addressed in the application. The requirements taken from § 50.34 are a subset of the information required of applicants for construction permits and operating licenses. Other requirements came from the original version of 10 CFR 52.47 or were developed by the Commission during the initial design certification reviews (e.g., SECY–93–087, ML003708021).

Although an applicant for design certification does not need to specify a particular site for the nuclear power plant, as in a combined license application, it does need to identify the site parameters, under paragraph (a)(1),

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that the standard nuclear power plant is designed to meet, e.g., postulated values for the safe-shutdown earthquake response spectra and maximum tornado wind speed. These parameters are usually selected to envelop a large portion of existing nuclear plant sites in the United States. Once the design is certified by the NRC, conformance of the actual site with the established site parameters must be demonstrated by the applicant for a combined license and verified by the NRC when the application is submitted.

Paragraph (a)(7) requires the applicant for design certification to describe its qualifications to design and analyze a standard nuclear power plant, which may become part of the bases for a future license.

Paragraph (a)(13) requires the applicant to provide the electric equipment list required by § 50.49(d). The NRC understands that the applicant may not be able to establish qualification files for all applicable components.

In its staff requirements memorandum (SRM) on SECY–90–377, "Requirements for Design Certification under 10 CFR part 52," dated February 15, 1991, the Commission directed the staff to ensure that the design certification process preserves operating experience insights in the certified design. Therefore, for plant designs that are based on or are evolutions of nuclear plants that have operated in the United States, paragraph (a)(22) requires the applicant to demonstrate how relevant operating experience insights, from NRC's generic letters and bulletins issued after the most recent revision of the applicable SRP and 6 months before the docket date of the application, have been incorporated into the plant design. Operating experience includes consideration of operating events and the reliability and performance of structures, systems, and components. If the application is for a design that is not based on or is not an evolution of a nuclear plant that operated in the United States, the applicant must demonstrate how insights from any relevant international operating experience have been incorporated into that plant design.

In its SRMs, dated June 26, 1990, and July 21, 1993, on SECY–90–16, "Evolutionary Light-Water Reactor Certification Issues and their Relationship to Current Regulatory Requirements," and SECY–93–087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Designs," respectively, the Commission approved NRC staff recommendations for selected preventative and mitigative design features for future light-water reactor designs. Paragraph (a)(23) requires the applicant to provide a description and analysis of those design features discussed in SECY–90–16 and SECY–93–087. Postulated severe accidents are not design-basis accidents (DBAs) and the severe accident design features do not have to meet the requirements for DBAs. However, the severe accident design features are part of a plant's design bases information.

Paragraph (a)(24) requires the applicant to provide a conceptual design for those design features that are outside the scope of the certified design, e.g., service water intake structure or ultimate heat sink.

Paragraph (a)(25) requires the applicant to describe the interface requirements for those design features that are outside the scope of the certified design, e.g., service water intake structure or ultimate heat sink. Paragraph (a)(26) requires justification that the interface requirements can be verified with the ITAAC for the plant.

Paragraph (a)(27) requires the applicant to provide a description of the design-specific PRA and its results. Guidance on how to meet the PRA information requirement will be provided in separate regulatory guidance documents.

Paragraph (b)(1) requires the applicant to provide the ITAAC that are necessary and sufficient to demonstrate that a facility that references the design certification has been constructed and will be operated in conformity with the design certification, the Atomic Energy Act of 1954, as amended, and the Commission's rules and regulations. These ITAAC will be a part of the Commission's verification program and must cover all of the design information that is within the scope of the certified design. ITAAC for the remaining design features that are outside of the scope of the certified design will be provided in a combined license application that references the design certification rule.

In its SRM on SECY–91–229, "Severe Accident Mitigation Design Alternatives for Certified Standard Designs," dated October 25, 1991, the Commission approved the staff's recommendation that design certification applicants assess SAMDAs for their standard plant designs. The Commission required SAMDA evaluations in order to achieve greater finality for the design features that are resolved in design certification rulemakings. For further explanation, see discussion in SECY–93–087, dated April 2, 1993. In order to implement this requirement, paragraph (b)(2) requires the applicant to provide a SAMDA evaluation for the standard plant design. This assessment is distinct from, and in addition to, the requirement in paragraph (a)(23) to provide a description and analysis of severe accident design features.

Paragraph (c)(1) requires an essentially complete scope of design in applications for evolutionary nuclear power plants. These plants are improved versions of light-water reactor designs that were in operation when part 52 was originally codified. Examples of evolutionary designs include General Electric's U.S. Advanced Boiling Water Reactor and Westinghouse's SP/90 and System 80+ designs. Evolutionary designs do not have to meet the design qualification testing requirements set forth in 10 CFR 50.43(e).

Paragraph (c)(2) requires applications for "advanced" nuclear power plants to provide an essentially complete scope of design and meet the design qualification testing requirements in 10 CFR 50.43(e). Advanced designs differ significantly from evolutionary light-water reactor designs or incorporate, to a greater extent than evolutionary designs do, simplified, inherent, passive, or other innovative means to accomplish their safety functions. Examples of advanced nuclear power plant designs include General Atomic's Modular High Temperature Gas-Cooled Reactor, General Electric's Simplified Boiling Water Reactor, and Westinghouse's AP600.

Paragraph (c)(3) requires applications for modular nuclear power plant designs to describe and analyze the possible operating configurations of reactor modules. Modular designs are defined in § 52.1. Modular plant designs are not portions of a single nuclear plant, rather they are separate nuclear power reactors with some shared or common systems.

Section 52.48 Standards for Review of Applications

This section sets forth the parts of 10 CFR that contain applicable requirements for the technical review of design certification applications. The applicability of these requirements to the design certification process is specified in the identified parts. The Commission recognizes that new designs may incorporate design features that are not addressed by the current standards set out in 10 CFR parts 20, 50 and its appendices, 51, 73, or 100, and that new standards may be required to address these new design features. The Commission will determine whether additional rulemakings are needed or appropriate to resolve generic safety

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issues that are applicable to multiple designs. On the other hand, new design features that are unique to a particular design could be addressed in the design certification rulemaking for that particular design.

Section 52.51 Administrative Review of Applications

This section sets forth the procedures for performing a notice and comment rulemaking for design certification. Paragraph (b) states that the Commission will determine, at its sole discretion, whether to hold a legislative hearing on the proposed design certification rule under the procedures in subpart O of 10 CFR part 2. Paragraph (c) states that proprietary information contained in an application for design certification will be given the same treatment that such information would be given in a proceeding on an application for a construction permit or an operating license under 10 CFR part 50. This gives the design certification applicant (vendor) an opportunity to treat elements of its design as trade secrets.

Section 52.53 Referral to the Advisory Committee on Reactor Safeguards (ACRS)

This section states that the application for design certification shall be sent to the ACRS for its review of safety issues.

Section 52.54 Issuance of Standard Design Certification

Paragraph (a) of this section sets forth the findings that the Commission must make in order to issue a design certification rule. Paragraph (b) requires that site parameters, design characteristics, and any additional requirements and restrictions be specified in the design certification rule. Previous DCRs set forth the additional requirements and restrictions in Section IV of the rule. Site parameters and design characteristics are defined in § 52.1 and can be specified in the design control document. These values will be used during the review of a combined license application that references the design certification rule to verify that the standard plant design conforms with the characteristics of the actual site and the design parameters used in the early site permit.

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

Section 52.55 Duration of Certification

The purpose of this section is to specify the duration that a standard design certification is valid for referencing in a combined license application.

Section 52.57 Application for Renewal

The purpose of this section is to set forth the process for applying for renewal of an existing design certification rule. Paragraph (a) specifies the time period for submitting an application for renewal and states that any person can apply for renewal. However, if the applicant for renewal is not the same person or entity that applied for the existing design certification, as identified in Section I of the DCR, then the new applicant is required to demonstrate that they have the capability to provide the detailed design for that certified nuclear power plant under § 52.63(c) or § 52.73(b).

Section 52.59 Criteria for Renewal

The purpose of this section is to identify the regulations that will be used to determine if an existing design certification should be renewed. Paragraph (a) states that the Commission will grant a request for renewal if the design complies with the regulations in effect at the time the certification was originally issued (see Section V of an existing design certification rule) and imposition of any new safety requirements on the design during a renewal proceeding will be governed by the backfit standards in paragraph (b).

Under paragraph (c), the applicant for renewal may request an amendment to the existing certified design to make some design changes provided that the new design meets the regulations in effect at the time that the amended, renewed design certification rule is issued and the changes do not require a major review or reanalysis of the new design. If the changes to the original design certification are so extensive that the NRC concludes an essentially new standard design is being proposed, then the applicant must submit an application for a new design certification under § 52.45.

Under paragraph (d), denial by the NRC of a request for renewal of a design certification does not prevent an applicant from submitting a new application for certification under § 52.45.

Section 52.61 Duration of Renewal

This section specifies the duration that a renewed design certification is valid for referencing in a combined license application.

Section 52.63 Finality of Standard Design Certifications

The purpose of this section is to set forth the process for amending or backfitting existing design certification rules (DCRs) or issuing orders to nuclear plants that referenced a DCR. This section also describes the finality of issue resolution under a design certification and the process for plant-specific departures from a certified design. This amendment process places a nuclear plant designer on the same footing as the Commission or any other member of the public (see 54 FR 15377, first column, April 18, 1989). Therefore, it cannot be said that this section makes it easier for a designer to amend design certification information than for the NRC to backfit the certified design. The amendment and backfitting process uses the phrase "certification information" in order to distinguish the rule language in the DCRs from the design certification information (*e.g.*, Tier 1 and Tier 2) that is incorporated by reference in the DCRs.

No matter who proposes it, a generic change under § 52.63(a)(1) will not be made to a DCR while it is in effect unless the change: (1) is necessary for compliance with Commission regulations applicable and in effect at the time the certification was issued; (2) is necessary to provide adequate protection of the public health and safety or common defense and security; (3) reduces unnecessary regulatory burden and maintains protection to public health and safety and common defense and security; (4) provides the detailed design information necessary to resolve selected design acceptance criteria; (5) corrects material errors in the certification information; (6) substantially increases overall safety, reliability, or security of a facility and the costs of the change are justified; or (7) contributes to increased standardization of the certification information.

Paragraphs (a)(1)(i) and (a)(1)(ii) did not change in the final rule. Paragraph (a)(1)(i) provides the compliance exception to the NRC's backfit process. Paragraph (a)(1)(ii) sets forth the special

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backfit criteria, which uses the adequate protection standard rather than the backfit standard in 10 CFR 50.109. The remaining paragraphs permit amendments of design certification information without meeting the special backfit requirement in § 52.63(a)(1)(ii).

Paragraph (a)(1)(iii) allows the Commission to change the design certification rule language to reduce unnecessary regulatory burdens, *i.e.*, incorporate the revised § 50.59 change criteria, or change the certification information if the change provides a reduction in regulatory burden and maintains protection to public health and safety and common defense and security. Maintaining protection generally embodies the same safety principles used by the NRC in applying risk-informed decision-making, *i.e.*, ensuring that adequate protection is provided, applicable regulations are met, sufficient safety margins are maintained, defense-in-depth is maintained, and that any changes in risk are small and consistent with the Commission's Safety Goal Policy Statement (refer to NRC's RG 1.174).

Paragraph (a)(1)(iv) allows for generic resolutions of design acceptance criteria (DAC) by amending DCRs. The DAC are a special type of ITAAC that are used to verify the resolution of design issues where sufficient design information was not provided in the design certification application. By generically resolving DAC with the amendment process, the Commission achieves resolution of additional design issues, achieves finality for those issue resolutions, and avoids repetitive consideration of those design issues in individual combined license proceedings. Also, the amendments will enhance standardization by further completing the certification information. The NRC staff will review the amendment application to ensure that the DAC are met and that the new design information conforms with the applicable regulations.

Paragraph (a)(1)(v) allows for generic resolutions of material errors in the certification information. This provision is only to be used to correct a material error, which is an error that significantly and adversely affects a design function or analysis conclusion described in the design control document (certification information). The Commission wants to correct material errors so that these errors will not have to be addressed in individual licensing proceedings.

Paragraph (a)(1)(vi) allows for generic amendments of certification information that will substantially increase the overall safety, reliability, or security of facility design, construction, or operation provided that the direct and indirect costs of implementation of the amendment are justified in view of this increased safety, reliability, or security. This amendment process will function similar to the backfitting process in 10 CFR 50.109.

Finally, paragraph (a)(1)(vii) allows for generic amendments that would increase the standardization of certification information in referencing applications. The Commission is still committed to achieving and maintaining the benefits of standardization. Therefore, the final rule allows for generic amendments of certification information through this additional process, provided that the amendment is applied to all plants that reference the DCR. This paragraph will allow applicants and licensees to request corrections or changes to certification information through a generic process rather than through individual licensing actions. In determining whether to codify a proposed amendment under this paragraph, the Commission will give special consideration to comments from applicants or licensees who referenced the DCR regarding whether they want to backfit their plants with these additional changes.

The process for amending DCRs will be a rulemaking with opportunity for public comment under paragraph (a)(2). As part of the rulemaking under § 52.63(a)(1), except for § 52.63(a)(1)(ii), the Commission will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration. The duration of the amended DCR will be for the same period of time as the original DCR and have the same expiration date.

Once a DCR is amended by rulemaking, under paragraph (a)(3) the changes will apply to all future applications referencing the DCR as well as all current plants referencing the design certification, unless the change has been rendered "technically irrelevant" through other action taken under paragraphs (a)(4) or (b)(1) of this section. Thus, standardization is maintained by ensuring that any amendment to a DCR is imposed upon all nuclear power plants referencing the design certification rule.

Paragraph (a)(4) sets forth the criteria that must be met before the Commission can impose new requirements by plant-specific order on a nuclear plant that references a DCR. Under this paragraph, the Commission must meet either the compliance or adequate protection backfit criteria and cite one or more special circumstances as defined in § 52.7. In addition, the Commission shall consider whether the special circumstances that justify the plant-specific order outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order. This additional requirement was added to ensure that the benefits of standardization will be preserved.

Paragraph (a)(5) sets forth the finality of matters that are resolved as part of a design certification rulemaking. Each of the DCRs have detailed provisions on the issues that were resolved for that plant design and detailed processes for changes to and departures from certification information (refer to Sections VI and VIII of appendices A, B, C, or D to part 52).

Paragraphs (b)(1) and (b)(2) provide processes for requesting exemptions and departures from certification information. As part of its adoption of a two-tiered rule structure (refer to SRM on SECY–90–377, dated February 15, 1991), the Commission codified detailed processes for changes to and departures from certification information in each of the design certification rules (refer to Section VIII of appendices A, B, C, or D to part 52). The processes for a specific certified design must be used when requesting exemptions and departures from certification information.

Paragraph (c) identifies the detailed design information that an applicant for a combined license must have completed and available for audit by the NRC. The NRC expects that design certification applicants (vendors) will have this information available during the review of a combined license application that references the certified design. Because a rule certifying a standard plant design does not belong to the designer (vendor), an applicant for a combined license that references the DCR could use a vendor other than the applicant that achieved the design certification. In that situation, the combined license applicant must acquire the detailed design information identified in paragraph (c) in order to demonstrate that the new vendor has the ability to provide the certified design and that the combined license applicant's design information is consistent with the design information for the DCR.

Subpart C—Combined Licenses

Section 52.71 Scope of Subpart

This section describes the scope of the requirements in this subpart. Under this subpart an applicant can request a combined construction permit and operating license with conditions (combined license) for a nuclear power

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facility. The combined license is essentially a combination of a construction permit, which requires consideration and resolution of many of the issues currently considered at the operating license stage, and a conditional operating license. Operation is allowed only after the Commission has made the finding that all acceptance criteria in ITAAC have been met.

The combined license application could describe a site and a custom design, or it could reference an early site permit (subpart A of part 52), a standard design certification (subpart B of part 52), a standard design approval (subpart E of part 52), or a reactor manufactured under a manufacturing licenses (subpart F of part 52) or a combination thereof. Although a pre-approved site and certified standard design need not be referenced for the combined license, maximum efficiency will result if site-related issues, as well as design-related issues, have been resolved before commencement of the combined license proceeding.

Section 52.73 Relationship to Other Subparts

The purpose of this section is to explain the relationship of the combined license process to the licensing processes in subparts A, B, E, and F of 10 CFR part 52.

Section 52.75 Filing of Applications

This section explains who can file, how to file, and the fees for NRC review of an application for a combined license.

Section 52.77 Contents of Applications; General Information

This section sets forth the type of general information that is required to be included in an combined license application, namely, the information required by 10 CFR 50.33. Section 50.33 requires that the application include information such as the name and address of the applicant, a description of the business or occupation of the applicant, citizenship information of the applicant, the class of license applied for, the use to which the facility will be put, the time for which the license is sought, financial qualification information, State and local emergency response plans, the earliest and latest dates for the completion of construction, and information about decommissioning funding. Section 50.33 also provides requirements for the handling of Restricted Data or other defense information in an application.

Section 52.79 Contents of Applications; Technical Information in Final Safety Analysis Report

The purpose of this section is to identify specific technical information to be included in the final safety analysis report as part of an application for a combined license. This generally includes the same information required of applicants for construction permits and operating licenses under 10 CFR part 50.

This section specifies the complete set of FSAR information needed for a combined license that is a stand-alone application, but also takes into account that certain information may already have been submitted and reviewed in those instances where the application references an early site permit (subpart A), a certified design (subpart B), a standard design approval (subpart E), a manufacturing license (subpart F), or some combination. The required FSAR information also includes requirements for descriptions of operational programs that need to be included in the FSAR to allow a reasonable assurance finding of acceptability. These additional requirements are in support of the Commission's direction to the staff in SRM–SECY–02–0067 dated September 11, 2002, "Inspections, Tests, Analyses, and Acceptance Criteria for Operational Programs (Programmatic ITAAC)," that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application. In this SRM, the Commission stated:

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

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

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

Accordingly, this section contains requirements for descriptions of operational programs and their implementation.

Paragraph (b) describes the information that is needed if the application references an early site permit. Although a combined license applicant referencing a certified design need not resubmit information or analyses submitted in connection with the early site permit, the combined license application FSARs must either include or incorporate by reference the SSAR for the early site permit. The SSAR must be included or incorporated into the combined license FSAR to ensure that matters addressed in the SSAR legally become part of the FSAR upon issuance of the combined license. This will also ensure that the information in the SSAR is subject to control under § 50.59 after issuance of the combined license. This provision is meant to convey that the combined license applicant referencing the early site permit does not need to resubmit, for NRC review, information or analyses that were already reviewed and resolved in the early site permit proceeding (such as information provided in responses to NRC requests for additional information). At the same time, this provision provides combined license applicants guidance as to what the combined license application must contain to be considered complete, including a requirement that it contain or incorporate the early site permit SSAR.

Because an early site permit applicant need not specify a particular nuclear plant design, the combined license application must demonstrate that the design of the facility falls within the site characteristics and postulated design parameters specified in the early site permit. If the application does not demonstrate that design of the facility falls within the site characteristics and design parameters of the early site permit, then, the applicant must request for a variance from the early site permit. Paragraph (b) requires that the application demonstrate that all terms and conditions in the early site permit, excluding terms and conditions imposed under § 50.36b, be satisfied by the date of issuance of the combined license. Any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license must be set forth as terms or conditions of the combined license. Early site permit conditions imposed under § 50.36b are to be addressed in the environmental report and not in the FSAR.

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Paragraph (b) also addresses emergency planning information submitted in a referenced early site permit and requires that the combined license application include any new or additional information to update or correct information provided with the early site permit and to discuss whether the new information may materially change the bases for compliance with the applicable NRC requirements. New information which materially changes the bases for compliance includes: (1) information which substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, as well as (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness in accordance with § 52.39(a)(1). New information that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for Commission to modify or impose new terms and conditions related to emergency preparedness would be subject to litigation during the combined license proceeding in accordance with § 52.39(c). This paragraph also addresses referenced early site permit emergency plans that incorporate existing emergency plans and requires the combined license application to identify changes to the emergency plans that constitute a decrease in effectiveness under 10 CFR 50.54(q). This requirement ensures that the NRC can review such changes to assess their impact on the emergency plans for the proposed combined license facility.

Paragraph (c) and (d) provide application requirements for a combined license that is referencing a standard design approval or a standard design certification, respectively. Similar to a combined license application referencing an early site permit, a combined license application referencing a design approval or design certification must either include or incorporate by reference the design approval or design certification FSAR. Because a design approval or design certification applicant need not specify a particular site, the combined license application must demonstrate that characteristics of the site fall within the site parameters specified in the design approval or design certification. In addition, the plant-specific PRA information must use the PRA information for the design certification and must be updated to account for site-specific design information and any design changes or departures. An applicant referencing a design certification must demonstrate that the interface requirements established for the design have been met. Applicants referencing either a design approval or a design certification must demonstrate that any terms and conditions in the design approval or requirements and restrictions in the referenced design certification rule will be satisfied by the date that the combined license is issued. Any terms or conditions of the design approval that cannot be met or satisfied by the time of issuance of the combined license must be set forth as terms or conditions of the combined license. Likewise, any requirements or restrictions of the design certification that cannot be met or satisfied by the time of issuance of the combined license must be set forth as terms or conditions of the combined license.

Paragraph (e) describes the information that is needed if the combined license application references one or more manufactured reactors. Similar to a combined license application referencing an early site permit, design approval, or design certification, a combined license application referencing one or more manufactured nuclear power reactors under subpart F or part 52 must either include or incorporate by reference the manufacturing license FSAR. Because a manufacturing license applicant need not specify a particular site for the installation of a manufactured reactor, the combined license application must demonstrate that the site parameters for the manufactured reactor are bounded by the site where the manufactured reactor is to be installed and used. In addition, the plant-specific PRA information must use the PRA information for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures. The combined license application must also demonstrate that the interface requirements established for the design have been met and that any terms and conditions in the manufacturing license will be satisfied by the date that the combined license is issued. Any terms or conditions of the manufacturing license that could not be met by the time of issuance of the combined license must be set forth as terms or conditions of the combined license.

Section 52.80 Contents of Applications; Additional Technical Information

This section covers the required technical contents of a combined license application that are not contained in the FSAR. These application contents include the proposed ITAAC, the environmental report, and information to address an applicant's request to perform activities at the site allowed by 10 CFR 50.10(e) before issuance of the combined license.

Paragraph (a) requires the application to include the proposed ITAAC and, if the application references an early site permit with ITAAC or a design certification, requires the applicant to use the ITAAC contained in the early site permit or design certification for the applicable portion of the combined license application. ITAAC that must be included are those that are necessary and sufficient to demonstrate that the facility has been constructed and will be operated in conformity with the combined license, the provisions of the Atomic Energy Act of 1954 and the Commission's rules and regulations. In addition, under Section 52.103(g), the Commission must find that all acceptance criteria specified in the license are met before facility operation. Because ITAAC are the sole source of acceptance criteria for subsequent resolution of items which cannot be fully evaluated prior to issuance of a combined license, it is essential that the combined license ITAAC include all significant issues that require satisfactory resolution before fuel loading.

This paragraph also provides an applicant for a combined license with a process for resolving certain acceptance criteria in one or more of the ITAAC before issuance of the combined license. This provision is included mainly to allow for completion of DAC at the combined license application stage because applicants might want to complete certain DAC before construction. DAC are special design certification rule ITAAC. DAC set forth processes and criteria for completing certain design information, such as information about the digital instrumentation and control system. Many DAC were originally written to be verified as part of the normal, post-combined license, ITAAC verification process. Completion of the design matters covered by DAC before the issuance of a combined license is consistent with the Commission's original concept for design certification and issuance of a combined license. When it adopted 10 CFR part 52, the Commission intended that a design certification contain final and complete design information. Allowing a finding of acceptable completion of DAC before issuance of a combined license is, therefore, consistent with the

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Commission's original intent. Second, completion of DAC before issuance of the combined license is consistent with the Commission's goal of resolving issues before construction. Determining whether DAC have been successfully completed before issuance of the combined license avoids the possibility that improperly completed DAC will result in the construction of improperly designed structures, systems, and components. Accordingly, a finding of successful completion of DAC may be made when a combined license is issued, if the combined license applicant demonstrates that the DAC have been successfully completed. This process would also allow findings on successful completion of inspections or tests of components procured before the issuance of the combined license.

Paragraph (b) requires a complete environmental report in accordance with 10 CFR 51.50(c).

Paragraph (c) requires that, if the applicant is requesting to perform any activities at the site allowed by 10 CFR 50.10(e), then the applicant must identify and describe the activities and propose a plan for redress of the site in the event that the activities are performed and either construction is abandoned or the combined license is revoked. This paragraph also requires the applicant to demonstrate that there is reasonable assurance that redress carried out under the plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws. These requirements attempt to limit, to the extent practicable, the environmental impact of any site work done in the case where construction of the nuclear power facility is not completed.

Section 52.81 Standards for Review of Applications

This section identifies the regulations that the NRC staff will use in performing its review of an application for a combined license.

Section 52.83 Finality of Referenced NRC Approvals; Partial Initial Decision of Site Suitability

This section describes the finality of regulatory products that may be referenced in a combined license application. Specifically, paragraph (a) states that the finality of matters resolved in a referenced early site permit, design certification, design approval, or manufacturing license are governed by the finality provisions in the respective subparts that address each of these regulatory processes. Paragraph (b) states that, while a partial decision on site suitability is in effect under 10 CFR 2.617(b)(2), the finality provisions in 10 CFR 2.629 govern the scope and nature of matters resolved in the proceeding.

Section 52.85 Administrative Review of Applications; Hearings

This section identifies the procedural requirements that apply to the mandatory combined license hearing. This section also identifies that, if an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing.

Section 52.87 Referral to the Advisory Committee on Reactor Safeguards (ACRS)

This section states that the ACRS will report on those portions of the application which concern safety.

Section 52.91 Authorization To Conduct Site Activities

The purpose of this section is to outline the activities that can be performed at the site by a combined license applicant. Paragraph (a) of this section discusses the authorization a combined license applicant needs to obtain in order to perform limited work activities at the site while the NRC is considering the combined license application in the case where a combined license applicant does not reference an early site permit that contains a redress plan. The requirements contained in paragraph (a) discuss work commonly referred to as a limited work authorization 1 (LWA–1) that is allowed in accordance with the requirements contained in 10 CFR 50.10(e)(1). These requirements do not allow the applicant to perform LWA–1 activities without first submitting a redress plan and obtaining the separate authorization required by 10 CFR 50.10(e)(1). Plans are expected to be modeled on the Midland Site Stabilization Report that was submitted on October 2, 1986 (ML061710504).

Paragraph (a) recognizes this possibility and notes that authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by 10 CFR 50.10(e)(2) and has determined that redress carried out under the site redress plan will return the site to an aesthetically acceptable and environmentally stable condition.

Paragraph (b) contains requirements for work commonly referred to as an LWA–2. An LWA–2 allows structural work for structures, systems, and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Because the design must be known to obtain authorization for LWA–2 activities, an LWA–2 is an option for a combined license applicant but not an option for an early site permit holder. A combined license applicant may request LWA–2 authority prior to the combined license being granted. Paragraph (b) recognizes this possibility and notes that authorization may be granted only after the presiding officer in the combined license makes the additional finding required by 10 CFR 50.10(e)(3)(ii), namely, that there are no unresolved safety issues relating to the LWA–2 activities.

Paragraph (c) of this section clarifies that, if work is performed either under an LWA–1, or LWA–2 or both, and the combined license application is subsequently withdrawn by the applicant or denied by the NRC, then the combined license applicant must redress the site in accordance with the terms of the site redress plan. Paragraph (c) of this section also provides the combined license applicant with the ability to redress the site for an alternate use that was not considered at the time that the original redress plan was prepared.

Section 52.93 Exemptions and Variances

The purpose of this section is to describe the process for combined license applicants to obtain exemptions and variances. If the request is for an exemption from any part of a referenced design certification rule, the Commission can grant the request only if it determines that the exemption complies with any exemption provisions in the referenced design certification rule, or with § 52.63 if there are no applicable exemption provisions in the referenced design certification rule. A request for an exemption that is outside the scope of a design certification rule must be processed in accordance with the requirements contained in § 52.7.

For the General Electric ABWR, Westinghouse System 80+, Westinghouse AP600, and Westinghouse AP1000 designs, these requirements are contained in Section VIII, "Processes for Changes and Departures," of appendices A, B, C, and D respectively, of 10 CFR part 52. Section VIII of these appendices discusses the process for exemptions from different portions of the design certification rule. The section-by-section analysis for these respective rules

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discuss requirements regarding processing of exemptions that are expected to be carried forward to future design certification rulemakings. Therefore, if applicable, the applicant should refer to the respective section-by-section analysis in the portion of the design certification rule that discusses exemptions for additional information. Exemptions requested in accordance with this section are subject to litigation in the same manner as other issues in the licensee hearing.

Paragraph (b) of this section sets forth the process for requesting variances from an early site permit if one is referenced in the combined license. Paragraph (c) sets forth the process for requesting variances from one or more design characteristics, site parameters, terms and conditions, or approved design of a manufactured reactor. Issuance of a variance is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

Section 52.97 Issuance of Combined Licenses

The purpose of this section is to set forth the process for issuing a combined license. Paragraph (a)(1) of this section sets forth the requirements relative to the Commission findings that must be made for granting of a combined license.

Paragraph (a)(2) of this section allows for completion of certain acceptance criteria in one or more of the ITAAC in a combined license being met prior to granting of the combined license. This paragraph could apply to DAC found in the applicable design certification rules. DAC set forth processes and criteria for completing certain design information, such as information about the digital instrumentation and control system. Paragraph (a)(2) would allow the Commission to make a finding of successful completion of DAC when a combined license is issued, if the combined license applicant demonstrates that the DAC have been successfully completed. This process would also allow findings on successful completion of inspections or tests of components procured before the issuance of a combined license. Paragraph (a)(2) notes that such a finding will preclude any required finding under § 52.103(g) with respect to that ITAAC.

Paragraph (b) requires the Commission to identify the ITAAC within the combined license that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations. This definition of what ITAAC are intended to accomplish is consistent with that contained in § 52.17 regarding early site permits, § 52.47 regarding design certifications and § 52.80, which are discussed above. If the combined license application references an early site permit with ITAAC related to emergency planning information, then the applicant must use these ITAAC in the emergency planning information submitted with the combined license application. If a combined license applicant references a design certification rule, the ITAAC contained in the license would be those contained in the design certification rule plus any additional ITAAC that were identified during the combined license review that were outside the scope of the certified design. If the Commission wishes to identify additional ITAAC that fall within the scope of the review of the referenced certified design it needs to meet the requirements contained in the design certification rule itself (see Section VIII.A.3 of appendix A, B, C, and D for the ABWR, System 80+, AP600, and AP1000) and the requirements contained in § 52.63. If a combined license applicant does not reference an early site permit or a certified design, then the ITAAC that are identified by the Commission for paragraph (b) of this section are those that were identified during the combined license review.

Section 52.98 Finality of Combined Licenses; Information Requests

This section covers the finality of combined license provisions and sets forth the requirements to modify the combined license after it has been issued. After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the backfit provisions of §§ 52.103 or 50.109, as applicable.

Paragraphs (b), (c), and (d) outline the applicability of the change processes in 10 CFR part 50, Section VIII of the design certification rules, and subpart F of 10 CFR part 52 to a combined license. The change processes in 10 CFR part 50 apply to a combined license that does not reference a design certification rule or a reactor manufactured under a manufacturing license. Section 52.98(c) states that the change processes in Section VIII of the design certification rules apply to changes within the scope of the referenced certified design. However, if the proposed change affects the design information that is outside of the scope of the design certification rule, the part 50 change processes apply unless the change also affects the design certification information. For that situation, both change processes may apply. If the combined license references a reactor manufactured under a subpart F manufacturing license, then changes to or variances from information within the scope of the manufactured reactor's design are subject to the change processes in § 52.171.

Paragraph (e) was added in 1992, and discussed in the section-by-section analysis (57 FR 60976; December 23, 1992), as following:

> This section has been amended with regard to making amendments to a combined license immediately effective under the so-called "Sholly Amendment." Under the Energy Policy Act, an amendment to a combined license can be made immediately effective if the Commission determines there are no significant hazards considerations. This section of the rule has been revised to incorporate the statutory provisions and previously issued Commission regulations implementing the "Sholly" amendment. The Commission, however, stresses that it will not look with favor upon license amendments to a combined license filed shortly before planned operation that could have the effect of undermining standardization or changing the scope of imminent or pending hearings on conformance issues.

Paragraph (f) states that any modification to a combined license is an amendment to the license and that there must be an opportunity for hearing on these amendments. Such amendments would be processed in accordance with the requirements contained in 10 CFR 50.90 and 50.91. In addition, if the applicant has referenced a certified design, or a reactor manufactured under a manufacturing license, additional requirements may apply. For example, a combined license that references an ABWR certified design may request an exemption from Tier 1 material in accordance with the provisions contained in Section VIII.A.4 of appendix A of 10 CFR part 52. In such a case, the licensee would have to process an exemption in accordance with the requirements contained in appendix A to part 52 and 10 CFR 52.63(b)(1) and a license amendment in accordance with paragraph (f) of this section.

Paragraph (g) which is analogous to §§ 52.39(f), 52.145(c), and 52.171(c),

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provides that NRC information requests must be evaluated before issuance to ensure that the burden to be imposed by the information request is justified in view of the potential safety significance of the issue to be addressed, except when the information requests seeks to verify compliance with the current licensing basis of the combined license. Information requests may be in the form of a new rule requiring submission of information (i.e., a new information collection and reporting requirement), or in the form of a NRC staff request for information. Information requests by the staff must be in accordance with 10 CFR 50.54(f) and must be approved by the EDO or his or her designee before the request may be issued.

Section 52.99 Inspection During Construction

The purpose of this section is to set forth the requirements to support the NRC's inspections during construction. A new § 52.99(a) has been added to require that the licensee submit to the NRC, no later than 1 year after issuance of the combined license or at the start of construction as defined in 10 CFR 50.10, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. This provision also requires the licensee to submit updates to the ITAAC schedule every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, licensees must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under § 52.99(c). The information provided by the licensee will be used by NRC in developing the NRC's inspection activities and activities necessary to support the Commission's finding whether all of the ITAAC have been met prior to the licensee's scheduled date for fuel load. Even in the case where there were no changes to a licensee's ITAAC schedule during an update cycle, the NRC expect the licensee to notify the NRC that there have been no changes to the schedule.

Section 52.99 has also been amended to incorporate rule language from the design certification rules in 10 CFR part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of appendix A to part 52). During the preparation of the design certification rules for the ABWR and System 80+ designs, the NRC staff and nuclear industry representatives agreed on certain requirements for the performance and completion of the inspections, tests, or analyses in ITAAC. In the design certification rulemakings, the Commission codified these ITAAC requirements into Section IX of the regulations. The purpose of the requirement in § 52.99(b) is to clarify that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been met.

Section 52.99(c)(1) requires the licensee to notify the NRC that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met. Section 52.99(c)(1) further requires that the notification contain sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met.

Section 52.99(c)(2) requires that, if the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel, the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee shall notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation (consistent with the Section 185.b requirement that the Commission, "prior to operation," find that the acceptance criteria in the combined license are met). The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel, and must provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met.

Section 52.99(c) ensures that: (1) The NRC has sufficient information to complete all of the activities necessary for the Commission to make a determination as to whether all of the ITAAC have been or will be met prior to initial operation; and (2) interested persons will have access to information on both completed and uncompleted ITAAC at a level of detail sufficient to address the AEA Section 189.a(1)(B) threshold for requesting a hearing on acceptance criteria. It is the licensee's burden to demonstrate compliance with the ITAAC and the NRC expects the information submitted under paragraph (c)(1) to contain more than just a simple statement that the licensee believes the ITAAC has been completed and the acceptance criteria met. The NRC expects the notification to be sufficiently complete and detailed for a reasonable person to understand the bases for the licensee's representation that the inspections, tests, and analyses have been successfully completed and the acceptance criteria have been met. The term "sufficient information" requires, at a minimum, a summary description of the bases for the licensee's conclusion that the inspections, tests, or analyses have been performed and that the prescribed acceptance criteria have been met. Furthermore, with respect to uncompleted ITAAC, it is the licensee's burden to demonstrate that it will comply with the ITAAC and the NRC expects the information that the licensee submits under paragraph (c)(2) to be sufficiently detailed such that the NRC can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. The term "sufficient information" requires, at a minimum, a summary description of the bases for the licensee's conclusion that the inspections, tests, or analyses will be performed and that the prescribed acceptance criteria will be met. In addition, "sufficient information" includes, but is not limited to, a description of the specific procedures and analytical methods to be used for performing the inspections, tests, and analyses and determining that the acceptance criteria have been met.

The NRC notes that, even though it did not include a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date, the NRC staff will require some period of time to perform its review of the last ITAAC once the licensee submits its notification that the ITAAC has been successfully completed and the acceptance criteria met. In addition, the Commission itself will require some period of time to perform its review of the staff's conclusions regarding all of the ITAAC and the staff's recommendations regarding the Commission finding under § 52.103(g). Therefore, licensees should structure their construction schedules to take into account these time periods.

A new paragraph (d) states the options that a licensee will have in the event that it is determined that any of the acceptance criteria in the ITAAC have not been met. If an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to

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successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under § 52.98(f). Also, if an activity that is subject to an ITAAC is not derived from a referenced standard design certification and the licensee has not demonstrated that the ITAAC has been met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under § 52.98(f).

Paragraph (e)(1) of this section indicates that the NRC is responsible for ensuring (through its inspection and audit activities) that the combined license holder performs and documents the completion of inspections, tests, and analyses in the ITAAC. When part 52 was first adopted by the Commission in 1989 (April 18, 1989; 54 FR 15372), the rule provided that the NRC staff shall ensure that the inspections, tests, and analyses in the ITAAC are performed, and did not refer to the Commission finding on acceptance criteria being met. The Commission revised the language in this portion of the rule in 1992 (December 23, 1992; 57 FR 60975) to reflect changes to Section 185 of the AEA made by Congress in the Energy Policy Act of 1992 (1992 EPA), which states:

> Following issuance of the combined license, the Commission shall ensure that the prescribed inspections, tests, and analyses are performed and, prior to operation of the facility, shall find that the prescribed acceptance criteria are met.

Thus, the revisions to this portion of the rule in 1992 simply reflected the language of the 1992 EPA. However, the Commission does not believe that Congress, by adopting language in Section 185 stating that the Commission shall ensure that the ITAAC are performed, intended to prohibit the Commission's long-standing practice of delegating to the NRC staff the responsibility for performing the necessary activities, including audits and inspections, to ensure that "the required inspections, tests, and analyses in the ITAAC are performed." Accordingly, the language from the 1992 rule change is retained in this final rule.

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

Section 52.103 Operation Under a Combined License

The purpose of this section is to set forth the requirements for operation under a combined license. This section has been previously discussed in a section-by-section analysis for the 1992 revisions to part 52 (57 FR 60976; December 23, 1992) which the NRC adopted in response to the Energy Policy Act of 1992. The 1992 section-by-section analysis states:

> In an effort to adhere as closely as possible to the new statutory requirements of the Energy Policy Act, the NRC has replaced most of its old § 52.103 with the text of section 2802 of that Act. Under the revised language, any request for a post-construction hearing must show, prima facie, both that one or more of the acceptance criteria are not or will not be met, and those specific operational consequences of nonconformance that would be contrary to providing reasonable assurance that the public health and safety will be adequately protected. The Commission may permit interim operation of a facility pending a hearing if it determines that this assurance exists. The Commission has the discretion to decide if any post-construction hearing will use formal or informal hearing procedures, and it must state publicly the reasons for choosing either set of procedures. The Commission must find, prior to operation of the facility, that the acceptance criteria have been met.

Paragraph (a) of this section is revised to require licensees to notify the NRC of its schedule date for initial loading of fuel no later than 270 days before the scheduled date and to notify the NRC of updates to its schedule every 30 days thereafter. This information will be used by the NRC to develop the notice of intended operation in the **Federal Register**, which must be published not less than 180 days before the licensee's initial fuel load date, as required by Section 189.a.(1)(B) of the AEA. In addition, paragraph (a) addresses the possibility that an applicant for a combined license may choose to resolve certain acceptance criteria in one or more of the ITAAC required by § 52.80 before issuance of the combined license. In such a case, if the Commission makes a finding in accordance with § 52.97 associated with these ITAAC at the time that a combined license is granted, these ITAAC would not be subjected to a hearing opportunity again under paragraph (a) of this section. The section-by-section analysis for § 52.97 discusses this issue in more detail.

Paragraph (b) provides the criteria that must be met for any request for a hearing on whether the facility complies or will comply with the acceptance criteria. The petitioner must set forth with reasonable specificity the facts and arguments which form the basis for the request. These provisions are designed to accord finality to the Commission's earlier decisions regarding the facility and to ensure that any proceeding is focused on significant safety issues.

Paragraph (c) requires the Commission to expeditiously either deny or grant any request for a hearing under this section. If a request is granted, the Commission must determine whether to allow interim operation of the facility based on reasonable assurance of adequate protection of the public health and safety.

Paragraph (d) provides that the Commission will determine the appropriate hearing procedures in accordance with 10 CFR part 2 for any hearing under paragraph (a) of this section. Under § 2.309, as adopted by the Commission in 2004 (69 FR 2182; January 14, 2004), such a hearing would ordinarily be conducted under subpart L of part 2. However, the Commission may direct, in the notice of required by paragraph (a) or in a subsequent order, that any hearing that may be conducted in a particular combined license proceeding under paragraph (a) use other, less formal hearing procedures, consistent with the requirements of the AEA. Any such Commission direction is consistent with the Commission's statement in the SOC for the 1989 final part 52 rulemaking (54 FR 15372, 15383; April 18, 1989) that any hearing held under former § 52.103(b)(2)(i) (§ 52.103(b) in this final rule) will use informal procedures to the maximum extent practical and permissible under law.

Paragraph (e) states that the Commission will, to the maximum extent possible, render a decision on issues raised in any hearing request within 180 days of the publication of the notice or by the anticipated date for initial fuel load, whichever is later.

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Paragraph (f) provides requirements related to the submittal of petitions to modify the terms and conditions of a combined license and states that fuel loading and operation under a combined license will not be affected by the granting of a petition unless the Commission makes an order immediately effective.

Paragraph (g) prohibits the licensee from operating the facility until the Commission makes a finding that the acceptance criteria in the combined license are met (except for acceptance criteria that the Commission found were met when the combined license was issued). The NRC believes that the rule should reflect, as closely as possible, the statutory requirement in Section 185.b of the AEA. Although the NRC has historically viewed "operation" as including loading of fuel into the reactor, the NRC believes it is not necessary to change the language of § 52.103(g) to continue the historical practice.

Paragraph (h) of this section incorporates rule language from the design certification rules in 10 CFR part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of appendix A to part 52). This paragraph states that ITAAC do not, by virtue of their inclusion in the design certification rule or combined license, constitute regulatory requirements after the licensee has received authorization to load fuel or for any renewal of the license. However, subsequent modifications to the facility or procedures described in the FSAR must comply with the requirements in § 52.98.

Section 52.104 Duration of Combined License

This section addresses the duration of a combined license which is a period not to exceed 40 years from the date that the Commission makes the finding that the acceptance criteria in the license are met, in accordance with § 52.103(g). Where the Commission has allowed operation during an interim period under § 52.103(c), the period of operation is not to exceed 40 years from the date allowing operation during the interim period. This provision implements Section 621 of the Energy Policy Act of 2005 which amended Section 103c. of the AEA. The AEA provided that the 40 year duration started on the date that the Commission authorized construction of the facility (i.e., the date of issuance of the combined license).

Section 52.105 Transfer of Combined License

This section states that a combined license may by transferred in accordance with 10 CFR 50.80, "Transfer of licenses." Section 50.80 provides the requirements regarding application for a license transfer. All license transfers must be approved by the Commission.

Section 52.107 Application for Renewal

This section states that an application to renew a combined license must be in accordance with 10 CFR part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants."

Section 52.109 Continuation of Combined License

This section, which is analogous to § 50.51, provides requirements for a combined license facility that has permanently ceased operations and states that the license continues in effect beyond the expiration date until the Commission notifies the licensee in writing that the license is terminated. During this period, the licensee is required to decommission and decontaminate the facility; maintain the facility, including the spent fuel, in a safe condition; and continue to follow the NRC's regulations and the provisions of the combined license.

Section 52.110 Termination of License

This section, which is analogous to § 50.82, provides requirements the termination of a combined license. These provisions include a requirement to notify the NRC within 30 days when a licensee has decided to permanently cease operations and to submit a certification to the NRC once fuel has been permanently removed from the reactor vessel. This section also requires decommissioning of the facility within 60 years of permanent cessation of operations and outlines requirements regarding decommissioning activities.

Subpart E—Standard Design Approvals

Section 52.131 Scope of Subpart

This section describes the scope of this process for design approvals of standard nuclear power plants or major portions thereof, i.e., a nuclear steam supply system or balance of plant. Under this subpart an applicant may request pre-approval of a standard nuclear power plant design, separate from a site review or other licensing action, and subsequently have that design approval referenced in an application to build a nuclear power plant. This licensing process was first adopted by the Commission in 1975 and has been used many times.

Section 52.133 Relationship to Other Subparts

The purpose of this section is to explain the relationship of the standard design approval process to the processes set forth in subparts B, C, and F of 10 CFR part 52, which provide for design certifications, combined licenses, and manufacturing licenses. The Commission continues to believe that the best approach for obtaining early resolution of design issues is through the design certification process in subpart B of this part. Applicants for a design approval have the option of also applying for design certification. Applicants for a combined license or a manufacturing license may reference a design approval.

Section 52.135 Filing of Applications

This section explains how to file an application for a standard design approval and how the fees for NRC's review of the application will be assessed. Applications are limited to final design information, in order to remove the unpredictability of issuing a construction permit that references only preliminary design information and initiating construction while the final design information is being completed. Approval of a final standard design ensures early consideration and resolution of technical matters by the NRC staff before there is any substantial commitment of resources, which will greatly enhance regulatory stability and predictability.

Section 52.136 Contents of Applications; General Information

This section identifies the general information that must be included in all applications.

Section 52.137 Contents of Applications; Technical Information

The purpose of this section is to identify the technical information that must be included in an application for a design approval. Paragraphs (a) and (c) describe information that must be included in the FSAR, which is included in the application, and paragraph (b) describes the information that must also be included in the application but does not need to be included in the FSAR. Applications for a major portion of the plant design, such as the nuclear steam supply system, only need to contain the technical information that is applicable to the major portion of the plant for which NRC staff approval is requested.

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Many of the requirements in this section were taken from 10 CFR 50.34 or are pointers to technical requirements in parts 20, 50, and 73 that must be addressed in the application. The requirements taken from § 50.34 are a subset of the information required of applicants for construction permits and operating licenses. Other requirements came from appendix O to part 50 or were created by the Commission during its simultaneous reviews of applications for design approvals and design certifications.

Although an applicant for design approval does not need to specify a particular site for the nuclear power plant, which is required in a combined license application, it does need to identify the site parameters that the standard nuclear power plant or major portion thereof is designed to meet, e.g., postulated values for the safe shutdown earthquake response spectra and maximum tornado wind speed. These parameters are usually selected to envelop a large portion of nuclear plant sites in the United States. Once the design is approved by the NRC, conformance of the actual site characteristics with the established site parameters must be demonstrated by an applicant referencing the design approval and verified by the NRC staff at the time that the referencing application is submitted, i.e., combined license application.

Paragraph (a)(7) requires the applicant for design approval to describe its qualifications to design and analyze a standard nuclear power plant.

In its staff requirements memorandum (SRM) on SECY–90–377, "Requirements for Design Certification under 10 CFR part 52," dated February 15, 1991, the Commission stated that information submitted in an application should incorporate the experience from operating events in current designs which we want to prevent in the future. Therefore, for plant designs that are based on or are evolutions of nuclear plants that have operated in the United States, paragraph (a)(22) requires the applicant to demonstrate how relevant operating experience insights, from NRC's generic letters and bulletins issued after the most recent revision of the applicable SRP and 6 months before the docket date of the application, have been incorporated into the plant design. Operating experience includes consideration of operating events and the reliability and performance of structures, systems, and components. If the application is for a design that is not based on or is not an evolution of a nuclear plant that operated in the United States, the applicant must demonstrate how insights from any relevant international operating experience have been incorporated into that plant design.

In its SRMs, dated June 26, 1990, and July 21, 1993, on SECY–90–16, "Evolutionary Light-Water Reactor Certification Issues and their Relationship to Current Regulatory Requirements," and SECY–93–087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Designs," respectively, the Commission approved NRC staff recommendations for selected preventative and mitigative design features for future light-water reactor designs. Paragraph (a)(23) requires the applicant to provide a description and analysis of those design features discussed in SECY–90–16 and SECY–93–87.

Paragraph (a)(U0) requires the application to describe the interfaces for those design features that are outside the scope of the approved design, e.g., service water intake structure or ultimate heat sink or, if the application is for approval of a major portion of the plant design, the interfaces between the nuclear steam supply system and the balance of plant.

Paragraph (a)(25) requires the applicant to provide a description of the design-specific PRA and its results. Guidance on meeting the PRA information requirements will be provided in separate regulatory guidance documents.

Paragraph (b) requires applications for "advanced" nuclear power plants to meet the design qualification testing requirements in 10 CFR 50.43(e). Advanced designs differ significantly from evolutionary light-water reactor designs or incorporate, to a greater extent than evolutionary designs do, simplified, inherent, passive, or other innovative means to accomplish their safety functions. Examples of advanced nuclear power plant designs include General Atomic's Modular High Temperature Gas-Cooled Reactor, General Electric's Simplified Boiling Water Reactor, and Westinghouse's AP600.

Section 52.139 Standards for Review of Applications

This section sets forth the parts of 10 CFR that contain applicable requirements for the technical review of applications for a design approval. The applicability of these requirements is specified in the identified parts. The Commission recognizes that new designs may incorporate design features that are not addressed by the current standards in 10 CFR parts 20, 50 and its appendices, 73, or 100 and that new standards may be required to address these new design features. The Commission will determine whether rulemakings are needed or appropriate to resolve generic safety issues that are applicable to multiple designs.

Section 52.141 Referral to the Advisory Committee on Reactor Safeguards (ACRS)

This section states that the application for design approval shall be sent to the ACRS for its review of safety issues.

Section 52.143 Staff Approval of Design

This section states that upon completion of the NRC staff's review of the standard design and receipt of a letter report from the ACRS, the staff shall issue a final safety evaluation report (FSER) and make that report available on the NRC's Web site. Also, if the FSER demonstrates that the standard design is acceptable, the Director of the Office of New Reactors or the Office of Nuclear Reactor Regulation may issue a final design approval with appropriate terms and conditions. The NRC's approval of a standard design is commonly referred to as an FDA because it is an approval of final design information.

Section 52.145 Finality of Standard Design Approvals; Information Requests

This section states that a valid FDA must be relied upon by the ACRS and NRR in any review of a license application that references the FDA unless significant new information substantially affects the staff's FSER. The Commission, Atomic Safety Licensing Board Panel, or presiding officers are not bound by NRC staff determinations in the FDA or FSER for the standard plant design. Therefore, there is no issue preclusion in the mandatory hearing for a combined license that references an FDA. Generic changes to the standard design can be made as a compliance backfit or under the backfit process in 10 CFR 50.109. Under paragraph (c), the justification for requests for information to FDA holders must be approved by the EDO or his or her designee, in accordance with the process set forth in 10 CFR 50.54(f).

Section 52.147 Section Duration of Design Approval

The purpose of this section is to specify the time period that an FDA can be referenced in a construction permit, operating license, combined license, or manufacturing license application.

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Subpart F—Manufacturing Licenses

Section 52.151 Scope of Subpart

This new section is analogous to the "scope of subpart" sections in subparts A through C of part 52 (e.g., §§ 52.13, 52.41, 52.71). Section 52.151 describes the general subject matter of subpart F as the requirements and procedures applicable to NRC issuance of licenses authorizing the manufacture of nuclear power reactors to be installed at sites not identified in the manufacturing license application. This subpart does not cover the manufacture of subcomponents (e.g., a pump or a reactor pressure vessel) or major subassemblies (e.g., an integrated module consisting of a pump, piping and instrumentation and control) for installation in a nuclear power plant, either on a specific site, or being delivered for integration into a nuclear power plant under a manufacturing license issued under this subpart. For purposes of this subpart, a manufactured "nuclear power reactor" would not include site-specific SSCs such as the site foundation or SSCs related to the ultimate heat sink.

Section 52.153 Relationship to Other Subparts

This new section is analogous to the "relationship to other subpart" sections in subparts A through C of part 52 (e.g., §§ 52.13, 52.43, 52.73). Section 52.153 explains how this subpart relates to other licensing processes in parts 50 and 52, as well as to the regulatory approvals in part 52.

A manufactured reactor may only be transported to and installed at a site for which either a construction permit under part 50 or a combined license under part 52 has been issued to a licensee, as stated in paragraph (a). However, the licensing requirements associated with transport of a manufactured reactor from its place of manufacture to the site where it is to be installed and operated are not addressed in this rulemaking.

The NRC will issue a manufacturing license only if it approves the final design of the reactor to be manufactured. Paragraph (b) provides that the manufacturing license applicant may reference either a standard design certification rule or a standard design approval, in order to speed the NRC's review of the manufacturing license application. The language of paragraph (b) has been corrected in the final rule by deleting the reference to "preliminary or final" design approvals, inasmuch as the final part 52 rule does not provide for preliminary design approvals.

Section 52.155 Filing of Applications

This new section is analogous to the "filing of applications" sections in subparts A through C of part 52 (e.g., §§ 52.15, 52.45, 52.75). Section 52.155 addresses who may file an application for a manufacturing license, the administrative requirements with respect to filing (referring to §§ 52.3 and 50.30), and the fees for filing and review of the application (referring to 10 CFR part 170). With respect to these matters, a manufacturing license application is no different than any other license application under parts 50 or 52, and the applicant shall comply with all of these administrative requirements (which have been revised as part of the final rule to refer, as necessary, to manufacturing licenses).

Section 52.156 Contents of Applications; General Information

This new section is analogous to the "contents of application; general information" sections in subparts A through C of part 52 (e.g., §§ 52.16, 52.46, 52.77). Section 52.156 requires that the applicant include the information set forth in § 50.33(a) through (d) and (j), which are the same information required to be supplied by applicants of construction permits, early site permits, operating licenses, and combined licenses. Paragraphs (a) through (d) of § 50.33 require an application to include information identifying the applicant, including its name, address, business or occupation, and certain corporate information, including whether it is owned, controlled, or dominated by an alien, foreign corporation, or foreign government. Paragraph (j) of § 50.33 requires the applicant to segregate and protect any Restricted Data or other defense information from unclassified information. Manufacturing license applicants should note that there are other NRC requirements governing Restricted Data or National Security Information in other parts of 10 CFR Chapter I, including 10 CFR parts 10, 50, and 95.

Section 52.157 Contents of Applications; Technical Information in Final Safety Analysis Report

This new section is analogous to the "contents of application; technical information" sections in subparts A through C of part 52 (e.g., §§ 52.17, 52.47, 52.79). Section 52.157 identifies the technical information that must be included in an application for a manufacturing license. These requirements were modeled on those subparts, in particular subpart B's provisions dealing with standard design certifications, because of the commonality with respect to the nature and scope of NRC approval of the design in both regulatory processes. As with the existing part 50 licensing process, and part 52's combined license and standard design certification processes, the manufacturing license application must include an FSAR. The FSAR contains the information necessary for the NRC to determine the safety of the reactor design to be manufactured and the adequacy of the applicant's proposed means of assuring that the manufacturing conforms to the design. The FSAR must contain a level of detail sufficient to permit preparation of construction and installation specifications by an applicant who seeks to use the manufactured reactor, and for the NRC to prepare acceptance and inspection requirements.

The information required to be included in the manufacturing license FSAR is largely the same as what is required for a design certification or combined license, but the requirements have been modified as necessary to reflect the fact that the design and manufacture of a reactor is being approved by license, but that the reactor must be transported to a site and integrated into site specific plant elements in order to operate. In addition, unlike the case with a design certification, the NRC is not distinguishing between evolutionary plants versus more advanced plants with respect to the level of detail required to be developed to support the license application. The NRC expects that the designs of all manufactured plants will be completed at a level of detail sufficient for: (1) The holder of the manufacturing license to develop procurement, construction and installation specifications; and (2) the NRC to develop acceptance and inspection requirements.

Paragraph (a) requires that the FSAR contain the principal design criteria for the reactor to be manufactured, and references appendix A to 10 CFR part 50 as establishing minimum requirements for the principal design criteria for water-cooled nuclear power plants. The NRC expects to develop technology-neutral design criteria for non-light water cooled reactor designs in the future. This requirement was drawn from § 50.34(a)(3)(i).

Paragraph (b) requires that the FSAR describe the design bases and the relation of the design bases to the principal design criteria that are identified in accordance with paragraph (a). This requirement was drawn from § 50.34(a)(3)(ii).

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Paragraph (c) requires that the FSAR describe and analyze the structures, systems, and components of the reactor to be manufactured, with the objective of demonstrating that the necessary safety functions will be accomplished. This requirement was drawn from § 50.34(a)(1) and (b)(2), but modified to reflect the fact that a manufacturing license represents approval of a final reactor design.

Paragraph (d) requires that the FSAR describe the safety features that are engineered into the reactor. This requirement was drawn from § 50.34(a)(1)(ii)(D), but modified to reflect the fact that a manufacturing license represents approval of a final reactor design.

Paragraph (e) requires the FSAR to describe the kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20.

Paragraph (f) requires that the FSAR include that information necessary to establish that the design of the reactor to be manufactured complies with 18 delineated technical requirements in 10 CFR part 50. Applicants and licensees should note that the part 50 requirements listed in paragraph (f) do not constitute the sum total of requirements in part 50 for which either an applicant for or holder of a manufacturing license must comply with in its application and throughout the life of its license. Rather, the listed requirements in paragraph (f) simply represents *the minimum necessary content of the FSAR* for a manufacturing license. The part 50 requirements listed in paragraph (e) are mainly applicable to LWRs. Potential applicants and licensees should also note that the NRC may, in the future, adopt additional technical requirements in part 50 applicable to LWRs. If the NRC believes that future manufacturing license holder's compliance with that new requirement must be documented and controlled through the FSAR, the NRC will make a conforming change in § 52.157 to refer to the new part 50 requirement. A similar course would also be followed if the NRC backfits, in accordance with the finality provisions in § 52.171, the new requirement on existing manufacturing licenses.

Paragraph (f)(19) requires that the FSAR include the site parameters postulated for the design of the manufactured reactor. Although an applicant for a manufacturing license does not need to specify a particular site where the manufactured reactor will be integrated into a nuclear power plant, as in a combined license application, it does need to identify the site parameters, under paragraph (f)(20), that the manufactured reactor is designed to meet, e.g., postulated values for the safe-shutdown earthquake response spectra and maximum tornado wind speed. These parameters are usually selected to envelop a large portion of nuclear plant sites in the United States. Once the manufacturing license is issued by the NRC, conformance of the actual site with the established site parameters must be demonstrated by the applicant referencing the use of the manufactured reactor.

Paragraph (f)(20) requires the FSAR to describe the interface requirements for those design features that are outside the scope of the design of the manufactured reactor, e.g., service water intake structure or ultimate heat sink, and paragraph (f)(21) requires justification that compliance with the interface requirements in paragraph (g) can be verified through inspections or tests (which may be conducted at the plant where the manufactured reactor is utilized, or elsewhere, e.g., the place of manufacture) or analysis. This paragraph does not require, however, that the FSAR contain "acceptance criteria" for determining whether the interface requirements have been met.

Paragraph (f)(22) requires the FSAR to include a representative conceptual design for the nuclear power facility using the manufactured reactor. This will be used by the NRC in its review of the FSAR, to assess the adequacy of the interface requirements in paragraph (g) of this section, and to help the Commission in determining the adequacy of the site parameters and design characteristics to be included in the manufacturing license. The conceptual design will not, however, be approved as part of the manufacturing license and the Commission does not anticipate directly requiring a nuclear power plant utilizing the manufactured reactor to use the conceptual design. Instead, the Commission intends to use site parameters, design characteristics, ITAAC, and interface requirements to ensure that the manufactured reactor will be utilized safely at a specific nuclear power plant.

Paragraph (f)(23) requires the applicant to provide a description and analysis of design features to address prevention and mitigation of severe accidents, consistent with the Commission's SRM on SECY–91–229, "Severe Accident Mitigation Design Alternatives for Certified Standard Designs," dated October 25, 1991.

Paragraph (f)(U0) is reserved to accommodate any new requirement for the contents of an FSAR submitted as part of an application for a manufacturing license which the Commission may adopt in the future.

Paragraph (f)(25) requires FSARs for modular nuclear power plant designs to describe and analyze the various options for the configuration of the multi-reactor nuclear power plant. Modular nuclear power plant designs are defined in § 52.1. Modular designs are not portions of a single nuclear plant, rather they are separate nuclear reactors with some shared or common systems.

Paragraphs (f)(26)(i), (ii), (iii), and (v) focus on FSAR information necessary to demonstrate applicants technical, managerial, and organizational capability and resources to design and manufacture a nuclear power reactor consistent with the approved design, and in accordance with all applicable requirements.

Paragraph (f)(26)(iv) requires the FSAR to include proposed procedures for the preparation of the manufactured reactor for shipping, the conduct of shipping, and for verifying the condition of the manufactured reactor upon receipt at the site. However, the holder of the manufacturing license need not be responsible for implementing the procedures for verifying the condition of the reactor upon receipt at the site. The NRC will require the licensee whose application referenced the use of the manufactured reactor to implement the approved verification procedures (this could be done as a license condition). With respect to shipping, the holder of the manufacturing license may use an agent (e.g., a shipping company) to transport the reactor. To ensure that the shipping requirements in the manufacturing license are complied with by the third party transporter, the NRC has included a provision in § 52.167(c)(2) requiring the manufacturing license holder to include, in any contract governing the transport of a manufactured reactor from the place of manufacture to any other location, a provision requiring that the person or entity transporting the manufactured reactor to comply with all NRC-approved shipping requirements in the manufacturing license.

For plant designs that are based on or are evolutions of nuclear plants that have operated in the United States, paragraph (f)(29) requires the applicant to demonstrate how relevant operating experience insights, from NRC's generic letters and bulletins issued after the most recent revision of the applicable SRP and 6 months before the docket

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date of the application, have been incorporated into the design of the reactor to be manufactured. Operating experience includes consideration of operating events and the reliability and performance of structures, systems, and components. If the application is for a design that is not based on or is not an evolution of a nuclear plant that operated in the United States, the applicant must demonstrate how insights from any relevant international operating experience have been incorporated into that manufactured reactor design.

Paragraph (f)(31) requires that the FSAR include a description of the design—specific probabilistic risk assessment and its results.

Section 52.158 Contents of Application; Additional Technical Information

This new section is analogous, in organizational structure, to § 52.80, "Contents of application; additional technical information" in subpart C of part 52.

Paragraph (a) requires that the application include inspections, tests, and analyses that the licensee who will be placing the manufactured reactor on a site and operating the reactor shall perform and their associated acceptance criteria. The purpose of these ITAAC are to ensure that: (1) The reactor has been manufactured in conformance with applicable requirements; and (2) the manufactured reactor, as emplaced at the site and integrated into any site-specific portions of the nuclear power plant, will operate in conformance with the design characteristics in the manufacturing license, the license authorizing operation of the manufactured reactor, and applicable requirements. Paragraph (a)(3), which is analogous to § 52.80(a)(3), provides that if the manufacturing license references a standard design certification, the manufacturing license application may include a notification that one or more ITAAC in the referenced design certification rule has been met. In such a situation, the **Federal Register** notice of docketing a hearing required by § 52.163 must specifically indicate that the application includes such a notification.

Paragraph (b)(1) requires that the application include an environmental report meeting the requirements in 10 CFR 51.54, which specifies the environmental information that must be submitted by a manufacturing license applicant to support the NRC's NEPA review. The Commission notes that environmental report need not include a discussion of assessment of the benefits and impacts of constructing and operating the manufactured reactor or an evaluation of alternative energy sources, under § 52.163 and § 51.54.

Under § 51.54, the environmental report for a manufacturing license must address the costs and benefits of SAMDAs that could be incorporated into the design, and the bases for not including SAMDAs into the design. The SAMDA information that must be included is essentially the same information that must be provided to support an application for a standard design certification. However, if the application references a standard design certification, § 51.54 provides that the manufacturing license's environmental report need not include the SAMDA evaluation. In such a case, the SAMDA determination in the EA for the referenced design certification would have finality in the manufacturing license proceeding, in accordance with § 52.63.

Section 52.159 Standards for Review of Applications

This new section is analogous to the "standards for review of applications" sections in subparts A through C of part 52 (e.g., §§ 52.18, 52.48, 52.81). Section 52.159 identifies the regulations that the NRC will use in reviewing an application for a manufacturing license. The NRC recognizes that reactors to be manufactured under a manufacturing license may incorporate design features which are inconsistent with current requirements in 10 CFR Chapter I, and may require exemptions from current requirements. Such exemptions would be granted as part of the NRC's issuance of the manufacturing license, together with alternative requirements (analogous to the "applicable regulations" provisions in the current design certifications rules, 10 CFR part 52, appendices A–D, Section V).

Section 52.161 Reserved

This section is reserved to accommodate any new requirements on the application process for manufacturing license which the NRC may adopt in the future.

Section 52.163 Administrative Review of Applications; Hearings

This new section is analogous to the "administrative review of applications" sections in subparts A through C of part 52 (e.g., §§ 52.21, 52.51, 52.85). Section 52.163 specifies that the procedural requirements in 10 CFR part 2 apply to the NRC's processing of an application for a manufacturing license, including docketing of the initial application.

Section 52.163 reiterates the § 2.105 requirement that the NRC publish in the **Federal Register** a notice of proposed action on the application. Apart from the required **Federal Register** notice, the Commission also expects to publish on the NRC's Web site notice of docketing of the application and the opportunity to intervene in the proceeding, consistent with the Commission's discussion in the 2004 final part 2 rulemaking (January 14, 2004; 69 FR 2182, 2198–99). The section makes clear, consistent with § 51.54, that the environmental report submitted by the manufacturing license applicant need not contain an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources.

Finally, this section indicates that the hearing on the manufacturing license application will be governed by the procedures in part 2, subparts C, G, L, and N. The Commission notes that although subpart G is listed in this paragraph, it is unlikely that there would be contentions meeting the criteria in § 2.310 (and reiterated in § 2.700) for conduct of the hearing under subpart G. This is because the primary focus of the manufacturing license proceeding is on the adequacy of the design to be manufactured, and the nature of issues which are most likely to be raised on the design would not ordinarily involve issues of material fact relating to either: (1) The occurrence of a past activity, where the credibility of an eyewitness may reasonably be expected to be at issue; or (2) issues of motive or intent of the party or eyewitness which are material to the resolution of the contested matter.

Section 52.165 Referral to the Advisory Committee on Reactor Safeguards (ACRS)

This new section is analogous to the "Referral to the Advisory Committee on Reactor Safeguards" sections in subparts A through C of part 52 (e.g., §§ 52.21, 52.53, 52.87). It provides that the ACRS will have the same role with respect to manufacturing licenses that it has for other nuclear power plant licenses, in that it will report on those portions of the application which concern safety.

Section 52.167 Issuance of Manufacturing License

This new section is analogous to the "issuance" sections in subparts A through C of part 52 (e.g., §§ 52.24, 52.54, 52.97). Paragraph (a) sets forth the timing of issuance of a manufacturing license and the findings that the Commission must make in

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order to issue the manufacturing license. The findings that must be made are similar to those necessary to issue a construction permit, inasmuch as construction is analogous to manufacturing. The Commission notes that it reserves the right to withhold issuance of the manufacturing license, even if all the rules and regulations of the Commission have been satisfied, based on public health and safety or common defense and security information or considerations not adequately addressed in the Commission's rules and regulations.

Paragraph (b) identifies the specific limitations that the Commission will include in each manufacturing license. They include technical specifications for the operation of each manufactured reactor, site parameters, design characteristics, and interface requirements, which are to be used by the applicant for and holder of the license referencing the use of the manufactured reactor(s). Ordinarily, the limitations to be included in the manufacturing license would be derived from the manufacturing license application, but the NRC may modify the proposed limitations based upon the NRC's review.

Paragraph (c) restricts the holder of the manufacturing license from transporting or allowing to be removed from the place of manufacture the manufactured reactor except to the site of a licensee who holds either a construction permit or combined license referencing the use of that manufactured reactor.

Section 52.169 Reserved

This section is reserved to accommodate any new requirements on either the issuance of, or activities authorized under a manufacturing license which the Commission may adopt in the future. Any new requirements adopted after issuance of a manufacturing license, which are made applicable to that manufacturing license, would have to satisfy the finality restrictions in § 52.171.

Section 52.171 Finality of Manufacturing Licenses; Information Requests

This new section is analogous to the variously entitled sections addressing finality and special backfitting protections which are in subparts A through C of part 52 (e.g., §§ 52.39, 52.63, 52.98),[15] but is more generally modeled on the finality provision for standard design certifications. In general, paragraph (a) addresses backfitting and finality restrictions on the NRC, paragraph (b) addresses finality and standardization restrictions applicable to the licensee (i.e., the holder the manufacturing license), and paragraph (c) establishes restrictions on certain NRC information collections with respect to the manufacturing license.

Paragraph (a)(1) states that the Commission may not modify, rescind, or impose new requirements on the design of a nuclear power reactor being manufactured, or new requirements for the manufacture of the nuclear power reactor, unless the Commission determines that a modification is necessary to either bring the design or the manufacture of the reactor into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security. This restriction on the Commission applies, *inter alia*, in construction permit, operating license, and combined license proceedings which reference the use of the manufactured reactor. It also applies in any enforcement proceeding initiated by the NRC, or in a rulemaking which proposes to apply new or changed requirements to reactors which have already been manufactured, as well as any reactors yet to be manufactured under the manufacturing license. However, the restrictions in paragraph (a)(1) do not apply to NRC information requests directed at either the manufacturing license holder, or to any holder of a license referencing the use of a manufactured reactor; such information requests are governed by paragraph (c) of this section.

Paragraph (a)(2) provides that any modification to the design of a manufactured nuclear power reactor which is imposed by the Commission under paragraph (a)(1) of this section will be applied to all reactors manufactured under the license, including those that have already been manufactured, transported, sited, and are in operation. The only exception would be for those reactors to which the Commission-ordered modification had been rendered technically irrelevant by action taken under paragraph (b) of this section, *i.e.*, either the holder of the manufacturing license has requested a change to the design approved in the manufacturing license (which ordinarily would apply only to reactors manufactured after Commission approval of the change), or the holder of a license referencing the use of the manufactured reactor has obtained Commission approval for a change to the design of the specific manufactured reactor(s) utilized by that licensee.

Paragraph (a)(3) delineates the nature of finality associated with the referencing of a manufactured reactor in subsequent NRC licensing proceedings. This paragraph provides that finality is accorded to those matters resolved in the proceeding on the issuance or renewal of the manufactured reactor. These matters resolved include the adequacy of the design of the manufactured reactor and the acceptability and completeness of the ITAAC required by § 52.158(a)(1) to be performed by the licensee operating the reactor. The matters resolved also include the SAMDA evaluation prepared by the Commission in compliance with its obligations under NEPA. This finality extends to both the Commission's determinations with respect to specific SAMDA features included in the design of the manufactured reactor, as well as the Commission's determinations regarding the lack of need for any other SAMDA features. Finality is accorded in the following situations: (1) Issuance of a construction permit, operating license, combined license; (2) any hearing under § 52.103; and (3) enforcement hearings other than those proceedings initiated by the Commission under paragraph (a)(1).

Paragraph (b)(1) requires the holder of a manufacturing license to seek a prior NRC review and approval for any change to the design of the nuclear power plant authorized to be manufactured. The holder of the manufacturing license may not make a change to the approved design for manufacture through the provisions of § 50.59. A request for a change to the approved design must be in the form of a license amendment application, and the application will be processed in accordance with §§ 50.90 through 50.92. The Commission notes, however, that the procedures for no significant hazards consideration (NSHC) are not applicable to manufacturing licenses, inasmuch as Section 189.a.(2) of the AEA, which is the statutory authority for these procedures, does not apply to manufacturing licenses.

Paragraph (b)(2) requires a holder of a license referencing the use of a manufactured reactor, who wishes to depart from the design characteristics, site parameters, terms and conditions,

[15] The finality provision in § 52.83 performs a different function than the finality sections cited above, in that it points back to, and thereby re-emphasizes, the primary finality provisions for each license or regulatory approval mechanism in part 52, e.g., the finality provision in § 52.39 for early site permits.

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or approved design of the manufactured reactor, to seek a departure from the NRC. The manner in which a departure is granted depends upon the timing of the request. If a departure is requested as part of the initial combined license application, the departure would be treated as part of the application and issued as part of the combined license. By contrast, if the same departure were sought after the combined license had been issued, then the licensee must apply for the departure in the form of a license amendment. The criteria for granting the departure is the exemption criterion in § 52.7; however, the departure itself is not considered an exemption (unless, of course, the departure also involves a non-compliance with an underlying Commission regulatory requirement in 10 CFR Chapter I). Thus, the Commission will not approve a departure unless the Commission finds, in addition to the routine exemption criteria in § 52.7, that special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. As explained earlier, these limitations are intended to maintain the standardization of manufactured reactors in operation to the extent practicable. The licensee may not depart from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor through the provisions of § 50.59.

Paragraph (c), which is analogous to §§ 52.39(d), 52.98(g), and 52.145(c), provides that NRC information requests must be evaluated before issuance to ensure that the burden to be imposed by the information request is justified in view of the potential safety significance of the issue to be addressed, except when the information requests seeks to verify compliance with the current licensing basis of either the manufacturing license or the manufactured reactor. This paragraph applies to information requests directed at either the holder of the manufacturing license or the holder of a license referencing the use of a manufactured reactor. Information requests may be in the form of a new rule requiring submission of information (i.e., a new information collection and reporting requirement), or in the form of a NRC staff request for information. Information requests by the staff must be in accordance with 10 CFR 50.54(f) and must be approved by the EDO or his or her designee before the request may be issued.

Section 52.173 Duration of Manufacturing License

This new section is analogous to the variously-entitled sections addressing duration (term) of each regulatory process in subparts A through C of part 52 (e.g., §§ 52.33, 52.61, 52.104). Under § 52.173, a manufacturing license may be issued for not less than 5 nor more than 15 years. Manufacturing of a new reactor may not commence less than 3 years before the expiration of the manufacturing license, even though a timely application for renewal has been filed in accordance with § 52.177. However, if a timely application for renewal of the manufacturing license has been docketed, manufacturing of uncompleted reactors whose manufacture commenced 3 years or more before the expiration date, may continue past the date of expiration of the license until the NRC acts upon the renewal application, consistent with the "Timely Renewal" doctrine of the Administrative Procedures Act. The NRC believes that timely renewal protection should only be provided to those applications which are of sufficient quality to be docketed. This is consistent with the requirement in § 2.109(b) requiring filing of a "sufficient" application for renewal of operating licenses as a prerequisite for the applicability of the timely renewal protection.

Section 52.175 Transfer of Manufacturing License

This new section is analogous to the variously entitled transfer sections in subparts A and C of part 52 (e.g., §§ 52.28, 52.105).[16] Section 52.175 provides that a manufacturing license may be transferred in accordance with § 50.80, which constitutes the Commission's common procedures and criteria governing transfers of nuclear power plant licenses. The matters to be addressed in a transfer are limited to the matters identified in § 50.80(b), and the transfer would not be an opportunity for the Commission to reconsider safety and environmental matters previously resolved, or to address new safety matters other than the narrow scope of matters identified in § 50.80(b).

Section 52.177 Application for Renewal

This new section is analogous to the "application for renewal" sections in subparts A through C of part 52 (e.g., §§ 52.29, 52.57, 52.107). Section 52.177 sets forth the content of an application for renewal, specifies the administrative requirements governing the application, addresses the effectiveness of a manufacturing license during the period of NRC's consideration of the renewal application, summarizes how an interested person may request a hearing on the renewal, and addresses the referral of the renewal application to the ACRS and the Commission's expectations with respect to the ACRS report on the application.

Section 52.179 Criteria for Renewal

This new section is analogous to the "criteria for renewal" sections in subparts A and B of part 52 (e.g., §§ 52.31, 52.59).[17] Section 52.179 provides that the Commission may grant renewal of a manufacturing license if the Commission determines that the license complies with the relevant provisions of the AEA, the Commission's regulations applicable and in effect at the time the manufacturing license was originally issued, and any new requirements which the Commission imposes which: (1) Are necessary for reasonable assurance of adequate protection to public health and safety or common defense and security; (2) are necessary for compliance with Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued; or (3) represent a substantial increase in overall protection of the public health and safety or common defense and security and the direct and indirect costs of implementation are justified in light of the increased protection. These "backfitting" restrictions are similar to—if somewhat narrower than—the backfitting restrictions applicable to renewal of standard design certification rules under subpart B of this part.

Reasonable assurance of adequate protection to public health and safety and common defense and security is provided under this regulatory approach, inasmuch as paragraph (b) allows the Commission to impose new requirements which are necessary for common defense and security, or are necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the manufacturing license was originally issued.

[16] A standard design certification is a rule, rather than a license. Accordingly, there is no "holder" of a standard design certification rule and no need for a provision addressing "transfer" of a standard design certification rule.

[17] Subpart C does not contain a "criteria for renewal" provision, inasmuch as the renewal would be governed by 10 CFR part 54, see § 52.107. Part 54 contains a provision, § 54.29, setting forth the standards for issuance of renewed licenses.

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Section 52.181 Duration of Renewal

This new section is analogous to the "duration of renewal" sections in subparts A and B of part 52 (e.g., §§ 52.33, 52.61).[18] Section 52.181 specifies the term of a renewed manufacturing license as not less than 5 nor more than 15 years from the date of expiration of the prior manufacturing license. Thus, a holder of a manufacturing license with an original term of 15 years, who is granted a 15-year renewal of the manufacturing license 4 years before expiration of the license, will obtain a renewed manufacturing license of 19 years, representing a 15-year term of the renewed license plus the 4 years remaining on its original license.

Subpart G—Reserved

This subpart is reserved for future use by the Commission.

Subpart H—Enforcement

This subpart contains two provisions, § 52.301 and § 52.303, which are comparable to former § 52.111 and § 52.113, and are analogous to provisions contained in other parts of 10 CFR Chapter I imposing requirements on regulated entities.

Section 52.301 reiterates, and provides notice to licensees and applicants under part 52 of the Commission's authority to obtain injunctions or other court orders for the violations enumerated in this paragraph.

Section 52.303 provides notice to all persons and entities subject to part 52 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 52. The regulations for which criminal penalties apply are limited to those which establish either a regulatory obligation or prohibition. Most of the regulations in part 52 are procedural or administrative in nature, and therefore were listed in § 52.113 as not being subject to criminal sanctions. The regulations in part 52 which are subject to criminal sanctions are §§ 52.4 . (Deliberate misconduct), 52.5 (Employee protection), 52.6 (Completeness of information), 52.25 (Extent of activities permitted), 52.35 (Use of site for other purpose), 52.91 (Authorization to conduct site activities), and 52.110 (Termination of license).

[18] Subpart C does not contain a "duration of renewal" provision, inasmuch as the renewal would be governed in all respects by 10 CFR part 54, see § 52.107. Part 54 contains a provision, § 54.31, governing the duration of renewed licenses.

Appendix A—U.S. Advanced Boiling Water Reactor

Refer to the section-by-section discussion in the final rule dated May 12, 1997 (62 FR 25800).

Appendix B—The System 80+ Design

Refer to the section-by-section discussion in the final rule dated May 21, 1997 (62 FR 27840).

Appendix C—The AP600 Design

Refer to the section-by-section discussion in the final rule dated December 23, 1999 (64 FR 72002).

Appendix D—The AP1000 Design

Refer to the section-by-section discussion in the final rule dated January 27, 2006 (71 FR 4464).

Appendix N—Combined Licenses for Nuclear Power Reactors of Identical Design

Appendix N of part 52 contains the Commission's procedures which may be used by one or more applicants for combined licenses under part 52, where the applications seek to construct and operate nuclear power reactors of identical design to be located at multiple sites. The comparable procedures governing applications for construction permits and operating licenses using identical nuclear power reactor designs remain in appendix N of 10 CFR part 50. Hearings for applications filed under appendix N in part 52, as well as part 50, are governed by subpart D of part 2. Thus, appendix N and subpart D of part 2 are integral to each other.

The regulations in appendix N of part 52 apply in two situations: (1) Where the same applicant seeks combined licenses at different sites utilizing the identical reactor design; and (2) where two or more different applicants each seek combined licenses at different sites utilizing the identical reactor design. In either situation, there is an identical reactor design. The Commission has deliberately used the term, "nuclear power reactor," in appendix N and subpart D of part 2—as distinguished from the term, "nuclear power plant"—to make clear that the site-specific elements, such as the service water intake structure or the ultimate heat sink, need not be identical in order for appendix N and subpart D to apply.

The Commission has conformed appendix N and subpart D of part 2 to use the term, "identical" nuclear power reactor design, and removed references to "duplicate" and "essentially identical." For purposes of appendix N and subpart D of part 2, designs for reactors are "identical," even if individual licensees request plant-specific departures or exemptions from a referenced standard design certification (or application). However, those plant-specific departures or exemptions are not part of the "common design." Therefore, the NRC's review of those departures and exemptions, as well as NRC hearings on those departures and exemptions, would be conducted separately as part of the safety review of each individual application, and would not be part of the hearing on the common design which would be conducted under subpart D of part 2.

Section 1

This is a new section specifying that its provisions apply to applicants for combined licenses under subpart C of part 52. Appendix N of part 50 would apply to applicants for construction permits and operating licenses who use identical reactor designs.

Section 2

This section, which is analogous to and derived from former § 2 of appendix N, specifies that each application submitted under this appendix must be submitted in accordance with the delineated Commission filing requirements. In addition, to ensure that the NRC is clearly informed that the applicants wish to have their application processed under appendix N and subpart D of part 2, this section requires: (1) That each application state the applicant's intent that the application be processed by the NRC under appendix N; and (2) that all of the applications to be treated together under this appendix be listed in each application. All of the applications must be filed simultaneously, which will facilitate NRC's administrative handling and technical review of the applications, as well as efficient conduct of the hearing process.

Section 3

This section, which is analogous to and derived from former § 3 of appendix N, specifies that combined license applications submitted under this appendix must include all of the information required to be submitted in a combined license application in §§ 52.77, 52.79, and 50.80(a) and (b), but makes clear that each of the applications must identify the common design. The common design may be (but is not limited to) a standard design certification under subpart B of part 52, a standard design approval, a "common custom design," or a manufactured reactor.

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The FSAR for each application must either incorporate by reference or include the FSAR for the common design, including, as applicable, the FSAR for the referenced design certification or manufactured reactor. "Include," means that the FSAR may not simply reference the common FSAR; the information from the referenced FSAR must be included within each application's FSAR.

Section 4

This is a new section specifying that each application must submit an environmental report which complies with the applicable provisions of part 51 with respect to the content of environmental reports. As an alternative, this section provides that one or more of the applicants' environmental reports may incorporate by reference a single environmental report describing the environmental impacts of the common design at each of the sites.

Section 5

This is a new section specifying that, upon a determination that each application is acceptable for docketing, each application will be docketed and a notice of docketing will be published in the **Federal Register** in accordance with 10 CFR 2.104. The notice of docketing must state that the application will be processed under the provisions of appendix N. Separate notices of docketing are contemplated, so that a problem with acceptance review of one application will not prevent the docketing and initiation of the NRC's technical review of the other applications determined to be sufficient and acceptable for docketing. This could occur, for example, if information, submitted by an applicant which is unrelated to the common design, is determined by the NRC to be insufficient. However, if the applications are determined to be acceptable for docketing, § 5 provides the Commission with the discretion to publish a single notice of docketing for those applications.

Section 6

This is a new section which provides that the NRC will prepare a separate draft and final EIS for each of the applications. Scoping may be conducted simultaneously but need not be conducted jointly (e.g., scoping for an application at site 1 need not be conducted as part of the same process as the scoping for an application for site 2), at least with respect to site-specific environmental issues. However, for environmental issues related to the common design, the NRC has the discretion to conduct joint scoping. The NRC staff is not, however, required to prepare a joint environmental impact statement for the common design.

This section also addresses the content of an EIS when the applications reference either a standard design certification or the use of a manufactured reactor of common design. In either case, the NRC has already prepared and finalized an EA which addresses SAMDAs. This SAMDA analysis is accorded finality under the provisions of §§ 52.63 and 52.171, respectively. Therefore, the EIS for each of the applications must reference the relevant environmental assessment containing the SAMDA analysis.

Section 7

This section, which is analogous to and derived from former § 1 of appendix N, provides direction to the ACRS with respect to their report on each of the combined license applications. The ACRS must issue a separate report on the safety of the common design, except in those instances where the applications are referencing either a standard design certification or manufactured reactor (of common design). In addition, the ACRS must issue a separate report for each application. This report must be limited to those matters which are not relevant to the common design. This will facilitate the NRC's licensing process by eliminating overlap and ensuring that the ACRS reports are carefully focused on the relevant safety issues.

Section 8

This is a new section, which provides that the Commission shall designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters (i.e., SAMDAs) relating to the common design. The presiding officer will conduct the hearing in accordance with subpart D of part 2. The presiding officer is required to issue a separate partial initial decision on matters relevant to the common design, consistent with 10 CFR 2.405 in subpart D of part 2. Appeals of the partial initial decision are governed by 10 CFR 2.341, as provided by 10 CFR 2.405. The NRC also notes that issues on the contested design may not be relitigated in a different phase of the hearing except on the basis of significant new information that substantially affects the conclusion(s) reached at the other phase or other good cause. See 10 CFR 2.406.

VII. Availability of Documents

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

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

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

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

The NRC staff contact. Nanette V. Gilles, Mail Stop O–4D9A, Washington, DC 20555–0001, 301–415–1180.

Document	PDR	Web	EPDR	NRC staff
Part 52 Rule, Cross-Reference Tables		X	ML062550246	X
Comments received	X	X	X	
Comment Summary Report			ML063450216	
Regulatory Analysis	X	X	ML071490350	X
Regulatory History Index for the proposed July 2003 rule			ML032810026	
Regulatory History Index for the March 13, 2006, proposed rule			ML062080575	

VIII. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" which became effective on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC, or adequacy category, Health and Safety (H&S). Category A includes program elements that are basic radiation protection standards or related

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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 includes 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 includes 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 includes program elements that address areas reserved to the Commission and cannot be relinquished to Agreement States pursuant to the Atomic Energy Act or provisions of Title 10 of the *Code of Federal Regulations*. An Agreement State may inform its licensees of certain of these NRC provisions through a mechanism that is appropriate under the State's administrative procedure laws as long as the State adopts these provisions solely for the purposes of notification, and does not exercise any regulatory authority pursuant to them. Category H&S include 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. In addition, a State should not adopt provisions that would preclude, or effectively preclude, a practice authorized by the Atomic Energy Act, and in the national interest. The proposed revisions are categorized as follows:

LIST OF CHANGES 10 CFR PART 52 FINAL RULEMAKING

Sections	Description new, changes	Compatibility designation	Comments regarding compatibility designation
10 CFR Part 1	Statement of Organization and General Information.	D	This provision is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions to reflect their organizational structure and may wish to inform its licensees of the provisions of this part through a mechanism that is appropriate under the State's administrative procedure laws.
10 CFR Part 2—Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders			
2.1	Scope	D, except portions of these provisions are NRC.	These provisions are designated Compatibility Category D because they do not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Part 52 standard design approvals, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.4—Definitions	Contested proceeding	D, except portions of the definition are NRC.	This definition is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt a similar definition that is compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and is consistent with their regulatory authority. Those portions of the definition that address areas reserved to the NRC, e.g., 10 CFR Part 52 activities, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
	License	NRC	This definition is designated Compatibility Category NRC because it addresses areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. For purposes of compatibility, States should use the language of the 10 CFR 20.1003 definition, except those portions of the definition that reference areas reserved to the NRC, e.g., 10 CFR Parts 50, 60, 63, and 72, are designated as a Compatibility Category NRC.
	Licensee	[D]	This definition also appears in 10 CFR 20.1003. For purposes of compatibility, the language of the Part 20 definition should be used where it is assigned to Compatibility Category D.

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LIST OF CHANGES 10 CFR PART 52 FINAL RULEMAKING—Continued

Sections	Description new, changes	Compatibility designation	Comments regarding compatibility designation
2.100 thru 2.390	All of the sections covered by Subparts A, B, and C.	D, except portions of these provisions are NRC.	These provisions are designated Compatibility Category D because they do not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Parts 50, 51, 52, 53, 54, 55, 60, 63, 72, 73, and 76, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.400 thru 2.629	All of the sections covered by Subparts D, E, and F.	NRC, for all of the sections.	These provisions are designated Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.800	Scope and applicability	D, except portions of these provisions are NRC.	These provisions are designated Compatibility Category D because they do not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Part 52, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.801	Initiation of rulemaking ..	D, except portions of these provisions are NRC.	These provisions are designated Compatibility Category D beoause they do not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Part 52, are designated as a Compatibility Category NRC. A State should not adopt previsions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.811	Filing of standard design certification application, required copies.	NRC	This provision is designated Compatibility Category NRC because it addresses an area reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.813	Written communications	NRC	This provision is designated Compatibility Category NRC because it addresses an area reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.815	Docketing and acceptance review.	NRC	This provision is designated Compatibility Category NRC because it addresses an area reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

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LIST OF CHANGES 10 CFR PART 52 FINAL RULEMAKING—Continued

Sections	Description new, changes	Compatibility designation	Comments regarding compatibility designation
2.817	Withdrawal of application.	NRC	This provision is designated a Compatibility Category NRC because it addresses an area reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.819	Denial of application for failure to supply information.	NRC	This provision is designated Compatibility Category NRC because it addresses an area reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.1202	Authority and role of NRC staff.	NRC	This provision is designated Compatibility Category NRC because it addresses an area reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
2.1211—[Removed]..			
10 CFR Part 10	Criteria and procedures for determining eligibility for access to restricted data or national security information or an employment clearance.	NRC for all sections	These provisions are designated Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 19—Notices, Instructions and Reports to Workers: Inspection and Investigations			
19.1	Purpose	D	This provision is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt a similar provision that is compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority.
19.2	Scope	D, except portions of the provisions in (a)(1), (a)(2), (a)(3), and (a)(4) are designated as NRC.	This provision is designated Compatibility Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Parts 50, 51, 52, 53, 54, 60, 63, 72, and 76, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
19.3—Definitions	License	D, except portions of the definition are NRC.	This definition is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt a similar definition that is compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and is consistent with their regulatory authority. Those portions of the definition that address areas reserved to the NRC, e.g., 10 CFR Parts 50, 51, 52, 53, 54, 55, 60, 63, 72, 73, and 76, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions. This definition appears in 10 CFR 20.1003. For purposes of compatibility, States should use the language of the Part 20 definition, which is assigned a Compatibility Category D.

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LIST OF CHANGES 10 CFR PART 52 FINAL RULEMAKING—Continued

Sections	Description new, changes	Compatibility designation	Comments regarding compatibility designation
	Regulated activities	D	This definition is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt a similar definition that is compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and is consistent with their regulatory authority.
	Regulated entities	D, except portions of the definition are NRC.	This definition is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt a similar definition that is compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and is consistent with their regulatory authority. Those portions of the definition that address areas reserved to the NRC are designated Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
	Worker	C	This definition is designated Compatibility Category C because of its role in effective communication, dose monitoring, and commerce (transboundary). A State should adopt definitions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. The essential objectives of this definition should be adopted.
19.11	Posting of Notices to workers.	C, except portions of paragraph (a), and all of paragraphs (b) and (e) are designated as NRC.	This provision is designated Compatibility Category C because it is needed to provide a minimum level of information to workers and to assure that this information is consistent from one jurisdiction to another since workers may work in multiple jurisdictions. A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. The essential objectives of this definition should be adopted. Those portions of paragraph (a) that reference 10 CFR Part 52 activities, and paragraphs (b) and (e) address areas reserved to the NRC, and are designated Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
19.14	Presence of representatives of licensees and workers during inspections.	C, except paragraph (a) is designated as NRC.	This provision is designated Compatibility Category C because it is needed to provide a minimum level of consistency from one jurisdiction to another since workers may work in multiple jurisdictions. A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Paragraph (a) addresses areas reserved to the NRC, and is designated Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
19.20	Employee protection	D, except portions of the provision are NRC.	This provision is designated Compatibility Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Parts 50, 52, 54, 60, 63, 72, and 76, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

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LIST OF CHANGES 10 CFR PART 52 FINAL RULEMAKING—Continued

Sections	Description new, changes	Compatibility designation	Comments regarding compatibility designation
19.31	Application for exemptions.	D	This provision is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority.
19.32	Discrimination prohibited	D	This provision is designated Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority.
10 CFR Part 20—Standards of Protection			
20.1002	Scope	D, except portions of the provision are designated as NRC.	This provision is designated Compatibility Category D because it does not meet any of the criteria of Category A, B, or C. A State may adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Parts 50, 52, 54, 60, 63, 72, and 76, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
20.1401	General provisions and scope.	C, except portions of the provision are designated as NRC.	This provision is designated Compatibility Category C because it is needed to provide a minimum level of consistency regarding decommissioning activities. A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. The essential objectives of these provisions should be adopted by States. Those portions of the provision that address areas reserved to the NRC, e.g., 10 CFR Parts 50, 52, 54, 60, 63, and 72, are designated as a Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
20.1406	Minimization of contamination.	C, except portions of paragraph (a) and all of paragraph (b) are designated as NRC.	This provision is designated Compatibility Category C because it is needed to provide a minimum level of safety regarding decommissioning activities. A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. The essential objectives of these provisions should be adopted by States. Those portions of paragraph (a) that reference 10 CFR Part 52 activities, and paragraphs (b) address areas reserved to the NRC, and are designated Compatibility Category NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

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LIST OF CHANGES 10 CFR PART 52 FINAL RULEMAKING—Continued

Sections	Description new, changes	Compatibility designation	Comments regarding compatibility designation
20.2203	Reports of exposures, etc., exceeding the limits.	C paragraphs (a) and (b). NRC paragraphs (c) and (d).	Paragraphs (a) and (b) are designated Compatibility Category C, because they are needed to provide a common understanding in collecting and reporting information on the regulation of agreement material on a nationwide basis. A State should adopt provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority. The essential objectives of these provisions should be adopted by States. Paragraphs (c) and (d) address NRC exclusive areas of authority are designated Compatibility Category NRC, and should not be adopted by States. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 21	Reporting of Defects and Noncompliance.	Not applicable for all sections.	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	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 26	Fitness for Duty Programs.	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
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 address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
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 address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
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 address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 54	Requirements for Renewal of Operating License for Nuclear Power Plants.	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.

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LIST OF CHANGES 10 CFR PART 52 FINAL RULEMAKING—Continued

Sections	Description new, changes	Compatibility designation	Comments regarding compatibility designation
10 CFR Part 55	Operators License	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 72	Licensing Requirements for Independent Storage of Spent Nuclear Fuel and High-level Radioactive Waste and Greater than Class C.	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 73	Physical Protection of Plants and Materials.	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 75	Safeguards on Nuclear Material—Implementation of US/IAEA Agreement.	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
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 address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 140	Financial Protection Requirements and Indemnity Agreements.	NRC for all sections	These provisions are designated a Compatibility Category NRC because they address areas reserved to the NRC. A State should not adopt provisions that would confer regulatory authority to the State in an area of exclusive NRC jurisdiction pursuant to the Atomic Energy Act, 10 CFR 8.4, 10 CFR Part 150, and other Federal laws, regulations, or provisions.
10 CFR Part 170	Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended.	D	These provisions are designated a Category D because they do not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority.
10 CFR Part 171	Annual Fees: For Reactor Licenses and Fuel Cycle Licenses and Material Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC.	D	These provisions are designated a Category D because they do not meet any of the criteria of Category A, B, or C. A State may adopt similar provisions that are compatible with the orderly pattern of regulation established by the Atomic Energy Act, as amended (Act) and are consistent with their regulatory authority.

IX. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this rule, the NRC is revising the procedural requirements for early site permits, standard design approvals, standard design certifications, combined licenses, and manufacturing licenses to make certain corrections and changes based on the experience of the previous design certification reviews and on discussions

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with stakeholders on these licensing processes. These procedural requirements for rulemaking do not establish standards or substantive requirements with which all applicants and licensees must comply. In addition, portions of this rulemaking make conforming changes to regulatory requirements throughout 10 CFR Chapter I, such as access to national security information and the procedures governing the conduct of hearings in proceedings. These changes also do not establish standards or substantive requirements with which all applicants and licensees must comply. Finally, portions of this rulemaking make conforming changes to technical requirements throughout 10 CFR Chapter I, in order to make clear their applicability to applicants and licensees under part 52. Inasmuch as the purpose of this rulemaking was not to establish or fundamentally alter these technical requirements, the Commission considers it impractical to perform a reassessment of the fundamental nature of these technical requirements in this rulemaking. In addition, this rule amends certain portions of the three design certification regulations in 10 CFR part 52, appendices A, B, and C (for U.S. ABWR, System 80+, and AP600 designs, respectively). Design certifications are not generic rulemakings in the sense that design certifications do not establish standards or requirements with which all applicants and licensees must comply. Rather, design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certification rulemakings are initiated by an applicant for a design certification, rather than the NRC. For these reasons, the Commission concludes that this action does not constitute the establishment of a standard that contains generally applicable requirements.

X. Environmental Impact—Categorical Exclusion

The NRC has determined that these amendments fall within the types of actions described as categorical exclusions 10 CFR 51.22(c)(1), (c)(2), and (c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.[19]

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

XI. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements contained in 10 CFR parts 21, 25, 50, 51, 52, and 54 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval numbers 3150–0035, 3150–0046, 3150–0011, 3150–0021, 3150–0151, and 3150–0155. The changes to 10 CFR parts 19, 20, 26, 55, 72, 73, 75, 95, and 140 do not contain new or amended information collection requirements. Existing requirements were approved by the Office of Management and Budget, approval numbers 3150–0044, 3150–0014, 3150–0146, 3150–0018, 3150–0132, 3150–0002, 3150–0055, 3150–0047, and 3150–0039.

The burden to the public for the information collections in 10 CFR part 52 is estimated to average 11,277 hours per response. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden to the records and FOIA/Privacy Services Branch (T–5 F53, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001), or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV;* and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202 (3150–0035, 3150–0046, 3150–0011, 3150–0151, and 3150–0155 with revised information collection requirements), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

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

XII. Regulatory Analysis

The Commission has prepared a regulatory analysis on this final rule. Consistent with the Regulatory Analysis Guidelines, the NRC performed an aggregate analysis of the rule. The analysis is based on the assumption that the NRC will receive 19 COL applications during the next 3 years and 1 COL application per year over the next 17 years. The net present value of the part 52 rule modifications are estimated to result in costs to the industry of $58,992 K and $30,952 K using a 3-percent and a 7-percent discount rate, respectively. The provisions of the rule relating to part 21 are estimated to result in net present value costs of $3,873 K and $2,363 K to the industry, using a 3-percent and a 7-percent discount rate, respectively. The net present value of the entire rule is estimated to result in net costs to the industry of $29,726 K and $204 K at a 3-percent and a 7-percent discount rate, respectively. In addition, the rule is estimated to be a one time net present value savings to the NRC of $10,443 K.

XIII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects only the licensing of nuclear power plants. The companies that will apply for an approval, certification, permit, site report, or license in accordance with the regulations affected by this rule do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XIV. Backfit Analysis

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

There are no current holders of combined licenses or manufacturing licenses that are protected by the backfitting restrictions in §§ 50.109, 52.39, 52.98, or 52.171. To the extent that this rule revises the requirements for future early site permits, standard design certifications, combined licenses, standard design approvals and manufacturing licenses for nuclear power plants, these revisions do not constitute backfits because they are prospective in nature and the backfit rule is not intended to apply to every NRC action which substantially changes the expectations of future applicants.

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The NRC issued the first early site permits prior to the effective date of this final part 52 rule. In addition, there are applications for early site permits currently being considered by the NRC. As discussed elsewhere, the NRC has included a "grandfathering provision" in the final part 52 rulemaking which provides that the early site permit provisions in subpart A of part 52 do not apply to early site permits whose applications were docketed before the effective date of the final part 52 rulemaking, unless requested by the early site permit applicant. This grandfathering provision prohibits any backfitting for these early site permits.

Other provisions in this rule would apply to currently-approved standard design approvals and certifications, but they are not protected by the backfitting restrictions in § 50.104 or § 52.63 because they are either corrections, administrative changes, or provide additional flexibility to applicants or licensees who might reference the design approvals or certifications, and thus constitute a voluntary alternative or relaxation.

Finally, some of the provisions in this rule represent conforming changes throughout 10 CFR Chapter I which are being made to reflect Commission adoption of design approvals and design certification processes which should have been made at the time the Commission first adopted these processes by rulemaking. While these conforming changes may, in some cases, affect the way in which a current design certification or design approval may be referenced, they do not directly affect the design approval nor are the conforming changes result in any inconsistency with the finality provisions in the design certifications or in part 52. Accordingly, the Commission believes that these conforming changes with respect to design approvals and design certifications do not raise new backfitting considerations.

XV. Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 1

Organization and functions (Government Agencies).

10 CFR Part 2

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

10 CFR Part 10

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

10 CFR Part 19

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

10 CFR Part 20

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

10 CFR Part 21

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

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping 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 recordkeeping 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 recordkeeping requirements, Security measures.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping 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

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relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Nuclear power plants and reactors.

■ For the reasons set forth in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52, 54, 55, 72, 73, 75, 95, 140, 170, and 171.

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

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

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

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

§ 1.43 Office of Nuclear Reactor Regulation.

* * * * *

(a) * * *

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

* * * * *

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

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

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

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97–425, 96 Stat. 2213, as amended (42 U.S.C. 10143(o)), sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 104, 105, 163, 183i, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Sections 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948–951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Section 2.205(j) also issued under Pub. L. 101–410, 104 Stat. 90, as amended by Section 3100(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2461 note). Subpart C also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332). Section 2.700a also issued under 5 U.S.C. 554. Sections 2.343, 2.346, 2.754, 2.712 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 3.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133), and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553, and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart M also issued under sec. 184 (42 U.S.C. 2234) and sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart N also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91–550, 84 Stat. 1473 (42 U.S.C. 2135).

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

§ 2.1 Scope.

* * * * *

(c) Imposing civil penalties under Section 234 of the Act;

(d) Rulemaking under the Act and the Administrative Procedure Act; and

(e) Standard design approvals under part 52 of this chapter.

■ 5. In § 2.4, the definitions of *contested proceeding, license* and *licensee* are revised to read as follows:

§ 2.4 Definitions.

* * * * *

Contested proceeding means—

(1) A proceeding in which there is a controversy between the NRC staff and the applicant for a license or permit concerning the issuance of the license or permit or any of the terms or conditions thereof;

(2) A proceeding in which the NRC is imposing a civil penalty or other enforcement action, and the subject of the civil penalty or enforcement action is an applicant for or holder of a license or permit, or is or was an applicant for a standard design certification under part 52 of this chapter; and

(3) A proceeding in which a petition for leave to intervene in opposition to an application for a license or permit has been granted or is pending before the Commission.

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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 paragraph of (a)(3), paragraph (a)(3)(ii), paragraph (a)(4), paragraph (a)(5), and paragraph (a–1) are revised to read as follows:

§ 2.101 Filing of application.

(a)(1) An application for a permit, a license, a license transfer, a license amendment, a license renewal, or a standard design approval, shall be filed with the Director of New Reactors or Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as prescribed by the applicable provisions of this chapter. A prospective applicant may confer informally with the NRC staff before filing an application.

(2) Each application for a license for a facility or for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee will be assigned a docket number. However, to allow a determination as to whether an application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license for a production or utilization facility is complete and acceptable for docketing, it will be initially treated as a tendered application. A copy of the tendered application will be available for public inspection at the NRC Web site, *http://www.nrc.gov,* and/or at the NRC

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Public Document Room. Generally, the determination on acceptability for docketing will be made within a period of 30 days. However, in selected applications, the Commission may decide to determine acceptability based on the technical adequacy of the application as well as its completeness. In these cases, the Commission, under § 2.104(a), will direct that the notice of hearing be issued as soon as practicable after the application has been tendered, and the determination of acceptability will be made generally within a period of 60 days. For docketing and other requirements for applications under part 61 of this chapter, see paragraph (g) of this section.

(3) If the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, determines that a tendered application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license for a production or utilization facility, and/or any environmental report required under subpart A of part 51 of this chapter, or part thereof as provided in paragraphs (a)(5) or (a–1) of this section are complete and acceptable for docketing, a docket number will be assigned to the application or part thereof, and the applicant will be notified of the determination. With respect to the tendered application and/or environmental report or part thereof that is acceptable for docketing, the applicant will be requested to:

* * * * *

(ii) Serve a copy on the chief executive of the municipality in which the facility or site which is the subject of an early site permit is to be located or, if the facility or site which is the subject of an early site permit is not to be located within a municipality, on the chief executive of the county, and serve a notice of availability of the application or environmental report on the chief executives of the municipalities or counties which have been identified in the application or environmental report as the location of all or part of the alternative sites, containing the following information, as applicable: Docket number of the application, a brief description of the proposed site and facility; the location of the site and facility as primarily proposed and alternatively listed; the name, address, telephone number, and email address (if available) of the applicant's representative who may be contacted for further information; notification that a draft environmental impact statement will be issued by the Commission and will be made available upon request to the Commission; and notification that if a request is received from the appropriate chief executive, the applicant will transmit a copy of the application and environmental report, and any changes to these documents which affect the alternative site location, to the executive who makes the request. In complying with the requirements of this paragraph, the applicant should not make public distribution of those parts of the application subject to § 2.390(d). The applicant shall submit to the Director of New Reactors or the Director of Nuclear Reactor Regulation an affidavit that service of the notice of availability of the application or environmental report has been completed along with a list of names and addresses of those executives upon whom the notice was served; and

* * * * *

(4) The tendered application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license will be formally docketed upon receipt by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, of the required additional copies. Distribution of the additional copies shall be deemed to be complete as of the time the copies are deposited in the mail or with a carrier prepaid for delivery to the designated addresses. The date of docketing shall be the date when the required copies are received by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate. Within 10 days after docketing, the applicant shall submit to the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, an affidavit that distribution of the additional copies to Federal, State, and local officials has been completed in accordance with the requirements of this chapter and written instructions furnished to the applicant by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate. Amendments to the application and environmental report shall be filed and distributed and an affidavit shall be furnished to the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, in the same manner as for the initial application and environmental report. If it is determined that all or any part of the tendered application and/or environmental report is incomplete and therefore not acceptable for processing, the applicant will be informed of this determination, and the respects in which the document is deficient.

(5) An applicant for a construction permit under part 50 of this chapter or a combined license under part 52 of this chapter for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility may submit the information required of applicants by part 50 or part 52 of the chapter in two parts. One part shall be accompanied by the information required by § 50.30(f) of this chapter, or § 52.80(b) of this chapter, as applicable. The other part shall include any information required by § 50.34(a) and, if applicable, § 50.34a of this chapter, or §§ 52.79 and 52.80(a), as applicable. One part may precede or follow other parts by no longer than 6 months. If it is determined that either of the parts as described above is incomplete and not acceptable for processing, the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days. Whichever part is filed first shall also include the fee required by §§ 50.30(e) and 170.21 of this chapter and the information required by §§ 50.33, 50.34(a)(1) or 52.79(a)(1), as applicable, and § 50.37 of this chapter. The Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, will accept for docketing an application for a construction permit under part 50 or a combined license under part 52 for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility where one part of the application as described above is complete and conforms to the requirements of part 50 of this chapter. The additional parts will be docketed upon a determination by the Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, that it is complete.

(a–1) *Early consideration of site suitability issues.* An applicant for a

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construction permit under part 50 of this chapter or a combined license under part 52 of this chapter for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility, may request that the Commission conduct an early review and hearing and render an early partial decision in accordance with subpart F of this part on issues of site suitability within the purview of the applicable provisions of parts 50, 51, 52, and 100 of this chapter.

(1) *Construction permit.* The applicant for the construction permit may submit the information required of applicants by the provisions of this chapter in three parts:

(i) Part one shall include or be accompanied by any information required by §§ 50.34(a)(1) and 50.30(f) of this chapter which relates to the issue(s) of site suitability for which an early review, hearing, and partial decision are sought, except that information with respect to operation of the facility at the projected initial power level need not be supplied, and shall include the information required by §§ 50.33(a) through (e) and 50.37 of this chapter. The information submitted shall also include:

(A) Proposed findings on the issues of site suitability on which the applicant has requested review and a statement of the bases or the reasons for those findings,

(B) A range of postulated facility design and operation parameters that is sufficient to enable the Commission to perform the requested review of site suitability issues under the applicable provisions of parts 50, 51, and 100, and

(C) Information concerning the applicant's site selection process and long-range plans for ultimate development of the site required by § 2.603(b)(1).

(ii) Part two shall include or be accompanied by the remaining information required by §§ 50.30(f), 50.33, and 50.34(a)(1) of this chapter.

(iii) Part three shall include the remaining information required by §§ 50.34a and (in the case of a nuclear power reactor) 50.34(a) of this chapter.

(iv) The information required for part two or part three shall be submitted during the period the partial decision on part one is effective. Submittal of the information required for part three may precede by no more than 6 months or follow by no more than 6 months the submittal of the information required for part two.

(2) *Combined license under part 52.* An applicant for a combined license under part 52 of this chapter may submit the information required of applicants by the provisions of this chapter in three parts:

(i) Part one shall include or be accompanied by any information required by §§ 52.79(a)(1) and 50.30(f) of this chapter which relates to the issue(s) of site suitability for which an early review, hearing, and partial decision are sought, except that information with respect to operation of the facility at the projected initial power level need not be supplied, and shall include the information required by §§ 50.33(a) through (e) and 50.37 of this chapter. The information submitted shall also include:

(A) Proposed findings on the issues of site suitability on which the applicant has requested review and a statement of the bases or the reasons for those findings;

(B) A range of postulated facility design and operation parameters that is sufficient to enable the Commission to perform the requested review of site suitability issues under the applicable provisions of parts 50, 51, 52, and 100; and

(C) Information concerning the applicant's site selection process and long-range plans for ultimate development of the site required by § 2.621(b)(1).

(ii) Part two shall include or be accompanied by the remaining information required by §§ 50.30(f), 50.33, and 52.79(a)(1) of this chapter.

(iii) Part three shall include the remaining information required by §§ 52.79 and 52.80 of this chapter.

(iv) The information required for part two or part three shall be submitted during the period the partial decision on part one is effective. Submittal of the information required for part three may precede by no more than 6 months or follow by no more than 6 months the submittal of the information required for part two.

* * * * *

■ 9. In § 2.102, paragraph (a) is revised to read as follows:

§ 2.102 Administrative review of application.

(a) During review of an application by the NRC staff, an applicant may be required to supply additional information. The staff may request any one party to the proceeding to confer with the staff informally. In the case of a docketed application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license of this chapter, the staff shall establish a schedule for its review of the application, specifying the key intermediate steps from the time of docketing until the completion of its review.

* * * * *

■ 10. Section 2.104 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**. The notice must be published at least 15 days, and in the case of an application concerning a construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter or a testing facility, at least 30 days before the date set for hearing in the notice.[1] In addition, in the case of an application for a construction permit, early site permit, or combined license for a facility of the type described in § 50.22 of this chapter, or a testing facility, the notice must be issued as soon as practicable after the NRC has docketed the application; provided, that if the NRC decides, under § 2.101(a)(2), to determine the acceptability of the application based upon its technical adequacy as well as completeness, the notice shall be issued as soon as practicable after the application has been tendered.

(b) The notice of hearing must state:

(1) The nature of the hearing;

(2) The authority under which the hearing is to be held;

(3) The matters of fact and law to be considered;

(4) The date by which requests for hearing or petitions to intervene must be filed;

(5) The presiding officer designated for the hearing, or the procedure that the Commission will use to designate a presiding officer for the hearing.

(c)(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

[1] If 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 § 50.22 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.

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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 an HLW repository at a geologic repository operations area under parts 60 or 63 of this chapter, for a license to receive and possess high-level radioactive waste at a geologic repository operations area under parts 60 or 63 of this chapter, and for a license under part 72 of this chapter to acquire, receive or possess spent fuel for the purpose of storage in an independent spent fuel storage installation (ISFSI) to the governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be located or conducted within an Indian reservation).

(2) The Secretary will transmit a notice of hearing on an application for a license under part 72 of this chapter to acquire, receive or possess spent fuel, high-level radioactive waste or radioactive material associated with high-level radioactive waste for the purpose of storage in a monitored retrievable storage installation (MRS) to the same persons who received the notice of docketing under § 72.16(e) of this chapter.

■ 11. In § 2.105, the introductory text of paragraphs (a) and (a)(4) are revised, and paragraphs (a)(12), (a)(13), 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, either a notice of intended operation under § 52.103(a) of this chapter and a proposed finding that inspections, tests, analysis, and acceptance criteria for a combined license under subpart C of part 52 have been or will be met, or a notice of proposed action with respect to an application for:

* * * * *

(4) An amendment to an operating license, combined license, or manufacturing license for a facility licensed under §§ 50.21(b) or 50.22 of this chapter, or for a testing facility, as follows:

* * * * *

(12) An amendment to an early site permit issued under subpart A of part 52 of this chapter, as follows:

(i) If the early site permit does not provide authority to conduct the activities allowed under § 50.10(e)(1) of this chapter, the amendment will involve no significant hazards consideration, and though the NRC will provide notice of opportunity for a hearing under this section, it may make the amendment immediately effective and grant a hearing thereafter; and

(ii) If the early site permit provides authority to conduct the activities allowed under § 50.10(e)(1) and the Commission determines under §§ 50.58 and 50.91 of this chapter that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing under § 2.106 of this chapter (if a hearing is requested, which will be held after issuance of the amendment).

(13) A manufacturing license under subpart F of part 52 of this chapter.

(b) * * *

(3) For a notice of intended operation under § 52.103(a) of this chapter, the following information:

(i) The identification of the NRC action as making the finding required under § 52.103(g) of this chapter;

(ii) The manner in which the licensee notifications under 10 CFR 52.99(c) which are required to be made available by 10 CFR 52.99(e)(2) may be obtained and examined;

(iii) The manner in which copies of the safety analysis may be obtained and examined; and

(iv) Any conditions, limitations, or restrictions to be placed on the license in connection with the finding under § 52.103(g) of this chapter, and the expiration date or circumstances (if any) under which the conditions, limitations or restrictions will no longer apply.

* * * * *

■ 12. In § 2.106, paragraphs (a) and (b) are revised to read as follows:

§ 2.106 Notice of issuance.

(a) The Director of New Reactors, Director of Nuclear Reactor Regulation, or Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the State and local officials specified in § 2.104(e) and publish a document in the **Federal Register** announcing the issuance of:

(1) A license or an amendment of a license for which a notice of proposed action has been previously published;

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter, or a testing facility, whether or not a notice of proposed action has been previously published; and

(3) The finding under § 52.103(g) of this chapter.

(b) The notice of issuance will set forth:

(1) In the case of a license or amendment:

(i) The nature of the license or amendment;

(ii) The manner in which copies of the safety analysis, if any, may be obtained and examined; and

(iii) A finding that the application for the license or amendment complies with the requirements of the Act and this chapter.

(2) In the case of a finding under § 52.103(g) of this chapter:

(i) The manner in which copies of the safety analysis, if any, may be obtained and examined; and

(ii) A finding that the prescribed inspections, tests, and analyses have been performed, the prescribed acceptance criteria have been met, and that the license complies with the requirements of the Act and this chapter.

* * * * *

■ 13. Section 2.109 is revised to read as follows:

§ 2.109 Effect of timely renewal application.

(a) Except for the renewal of an operating license for a nuclear power plant under 10 CFR 50.21(b) or 50.22, an early site permit under subpart A of part 52 of this chapter, a manufacturing license under subpart F of part 52 of this chapter, or a combined license under subpart C of part 52 of this chapter, if at least 30 days before the expiration of an existing license authorizing any activity of a continuing nature, the licensee files an application for a renewal or for a new license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

(b) If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 50.22 files a sufficient application for renewal of either an operating license or a combined license at least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

(c) If the holder of an early site permit licensed under subpart A of part 52 of this chapter files a sufficient application for renewal under § 52.29 of this chapter at least 12 months before the expiration of the existing early site permit, the

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existing permit will not be deemed to have expired until the application has been finally determined.

(d) If the licensee of a manufacturing license under subpart F of part 52 of this chapter files a sufficient application for renewal under § 52.177 of this chapter at least 12 months before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

■ 14. Section 2.110 is revised to read as follows:

§ 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

(a)(1) A submittal for a standard design approval under subpart E of part 52 of this chapter shall be subject to §§ 2.101(a) and 2.390 to the same extent as if it were an application for a permit or license.

(2) Except as specifically provided otherwise by the provisions of appendix Q to parts 50 of this chapter, a submittal for early review of site suitability issues under appendix Q to parts 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 parts 50 of this chapter, or for a standard design approval under subpart E of part 52 of this chapter, the Director of New Reactors or the Director of Nuclear Reactor Regulation shall publish in the **Federal Register** a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or other time as may be specified, for consideration by the NRC staff and ACRS in their review.

(c)(1) Upon completion of review by the NRC staff and the ACRS of a submittal for a standard design approval, the Director of New Reactors or the Director of the Office of Nuclear Reactor Regulation shall publish in the **Federal Register** a determination as to whether or not the design is acceptable, subject to terms and conditions as may be appropriate, and shall make available at the NRC Web site, *http://www.nrc.gov*, a report that analyzes the design.

(2) Upon completion of review by the NRC staff and, if appropriate by the ACRS, of a submittal for early review of site suitability issues, the NRC staff shall prepare a staff site report which shall identify the location of the site, state the site suitability issues reviewed, explain the nature and scope of the review, state the conclusions of the staff regarding the issues reviewed and state the reasons for those conclusions. Upon issuance of an NRC staff site report, the NRC staff shall publish a notice of the availability of the report in the **Federal Register** and shall make the report available at the NRC Web site, *http://www.nrc.gov*. The NRC staff shall also send a copy of the report to the Governor or other appropriate official of the State in which the site is located, and to the chief executive of the municipality in which the site is located or, if the site is not located in a municipality, to the chief executive of the county.

■ 15. Section 2.111 is revised to read as follows:

§ 2.111 Prohibition of sex discrimination.

No person shall on the grounds of sex be excluded from participation in, be denied a license, standard design approval, or petition for rulemaking (including a design certification), be denied the benefits of, or be subjected to discrimination under any program or activity carried on or receiving Federal assistance under the Act or the Energy Reorganization Act of 1974.

■ 16. In § 2.202, paragraph (e) is revised to read as follows:

§ 2.202 Orders.

* * * * *

(e)(1) If the order involves the modification of a part 50 license and is a backfit, the requirements of § 50.109 of this chapter shall be followed, unless the licensee has consented to the action required.

(2) If the order involves the modification of combined license under subpart C of part 52 of this chapter, the requirements of § 52.98 of this chapter shall be followed unless the licensee has consented to the action required.

(3) If the order involves a change to an early site permit under subpart A of part 52 of this chapter, the requirements of § 52.39 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

(4) If the order involves a change to a standard design certification rule referenced by that plant's application, the requirements, if any, in the referenced design certification rule with respect to changes must be followed, or, in the absence of these requirements, the requirements of § 52.63 of this chapter must be followed, unless the applicant or licensee has consented to follow the action required.

(5) If the order involves a change to a standard design approval referenced by that plant's application, the requirements of § 52.145 of this chapter must be followed unless the applicant or licensee has consented to follow the action required.

(6) If the order involves a modification of a manufacturing license under subpart F of part 52, the requirements of § 52.171 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

■ 17. In § 2.309, paragraphs (a), (f)(1)(i), (f)(1)(v), and (f)(1)(vi) are revised, a new paragraph (f)(1)(vii) is added, and paragraphs (g), (h)(2), and (i) are revised to read as follows:

§ 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

(a) *General requirements.* Any person whose interest may be affected by a proceeding and who desires to participate as a party must file a written request for hearing and a specification of the contentions which the person seeks to have litigated in the hearing. In a proceeding under 10 CFR 52.103, the Commission, acting as the presiding officer, will grant the request if it determines that the requestor has standing under the provisions of paragraph (d) of this section and has proposed at least one admissible contention that meets the requirements of paragraph (f) of this section. For all other proceedings, except as provided in paragraph (e) of this section, the Commission, presiding officer, or the Atomic Safety and Licensing Board designated to rule on the request for hearing and/or petition for leave to intervene, will grant the request/petition if it determines that the requestor/petitioner has standing under the provisions of paragraph (d) of this section and has proposed at least one admissible contention that meets the requirements of paragraph (f) of this section. In ruling on the request for hearing/petition to intervene submitted by petitioners seeking to intervene in the proceeding on the HLW repository, the Commission, the presiding officer, or the Atomic Safety and Licensing Board shall also consider any failure of the petitioner to participate as a potential party in the pre-license application phase under subpart J of this part in addition to the factors in paragraph (d) of this section. If a request for hearing or petition to intervene is filed in response to any notice of hearing or opportunity for hearing, the applicant/licensee shall be deemed to be a party.

* * * * *

(f) * * *

(1) * * *

(i) Provide a specific statement of the issue of law or fact to be raised or controverted, *provided further,* that the issue of law or fact to be raised in a request for hearing under 10 CFR 52.103(b) must be directed at demonstrating that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety;

* * * * *

(v) Provide a concise statement of the alleged facts or expert opinions which support the requestor's/petitioner's position on the issue and on which the petitioner intends to rely at hearing, together with references to the specific sources and documents on which the requestor/petitioner intends to rely to support its position on the issue;

(vi) In a proceeding other than one under 10 CFR 52.103, provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact. This information must include references to specific portions of the application (including the applicant's environmental report and safety report) that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief; and

(vii) In a proceeding under 10 CFR 52.103(b), the information must be sufficient, and include supporting information showing, *prima facie,* that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety. This information must include the specific portion of the report required by 10 CFR 52.99(c) which the requestor believes is inaccurate, incorrect, and/or incomplete (i.e., fails to contain the necessary information required by § 52.99(c)). If the requestor identifies a specific portion of the § 52.99(c) report as incomplete and the requestor contends that the incomplete portion prevents the requestor from making the necessary *prima facie* showing, then the requestor must explain why this deficiency prevents the requestor from making the *prima facie* showing.

* * * * *

(g) *Selection of hearing procedures.* A request for hearing and/or petition for leave to intervene may, except in a proceeding under 10 CFR 52.103, also address the selection of hearing procedures, taking into account the provisions of § 2.310. If a request/petition relies upon § 2.310(d), the request/petition must demonstrate, by reference to the contention and the bases provided and the specific procedures in subpart G of this part, that resolution of the contention necessitates resolution of material issues of fact which may be best determined through the use of the identified procedures.

(h) * * *

(2) Except in a proceeding under 10 CFR 52.103, the requestor/petitioner may file a reply to any answer. The reply must be filed within 7 days after service of that answer.

* * * * *

(i) *Decision on request/petition.* In all proceedings other than a proceeding under 10 CFR 52.103, the presiding officer shall, within 45 days after the filing of answers and replies under paragraph (h) of this section, issue a decision on each request for hearing/petition to intervene, absent an extension from the Commission. The Commission, acting as the presiding officer, shall expeditiously grant or deny the request for hearing in a proceeding under 10 CFR 52.103. The Commission's decision may not be the subject of any appeal under 10 CFR 2.311.

■ 18. In § 2.310, paragraph (j) is redesignated as paragraph (k), and a new paragraph (j) is added to read as follows:

§ 2.310 Selection of hearing procedures.

* * * * *

(j) Proceedings on a Commission finding under 10 CFR 52.103(c) and (g) shall be conducted in accordance with the procedures designated by the Commission in each proceeding.

* * * * *

■ 19. In § 2.339, paragraph (d) is revised to read as follows:

§ 2.339 Expedited decisionmaking procedure.

* * * * *

(d) The provisions of this section do not apply to an initial decision directing the issuance of a limited work authorization under 10 CFR 50.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization, a combined license under subpart C of part 52 of this chapter, or a manufacturing license under subpart F of part 52.

■ 20. Section 2.340 is revised to read as follows:

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

(a) *Initial decision—production or utilization facility operating license.* In any initial decision in a contested proceeding on an application for an operating license (including an amendment to or renewal of an operating license) for a production or utilization facility, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, any matter designated by the Commission to be decided by the presiding officer, and any matter not put into controversy by the parties, but only to the extent that the presiding officer determines that a serious safety, environmental, or common defense and security matter exists, and the Commission approves of an examination of and decision on the matter upon its referral by the presiding officer. Depending on the resolution of those matters, the Commission, the Director of Nuclear Reactor Regulation, or the Director of New Reactors, as appropriate, after making the requisite findings, will issue, deny or appropriately condition the license.

(b) *Initial decision—combined license under 10 CFR part 52.* In any initial decision in a contested proceeding on an application for a combined license (including an amendment to or renewal of a combined license) under subpart C of part 52 of this chapter, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and any matter designated by the Commission to be decided by the presiding officer. Depending on the resolution of those matters, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, after making the requisite findings, will issue, deny or appropriately condition the license.

(c) *Initial decision on finding under 10 CFR 52.103 with respect to acceptance criteria in nuclear power reactor combined licenses.* In any initial decision under § 52.103(g) of this chapter with respect to whether acceptance criteria have been or will be met, the presiding officer shall make findings of fact and conclusions of law

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on the matters put into controversy by the parties to the proceeding, and on any matters designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties shall be referred to the Commission for its determination. The Commission may, in its discretion, treat the matter as a request for action under 10 CFR 2.206 and process the matter in accordance with § 52.103(f). Depending on the resolution of those matters, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, will make the finding under 10 CFR 52.103, or appropriately condition that finding.

(d) *Initial decision—manufacturing license under 10 CFR part 52.* In any initial decision in a contested proceeding on an application for a manufactured license (including an amendment to or renewal of a combined license) under subpart C of part 52 of this chapter, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and any matter designated by the Commission to be decided by the presiding officer. Depending on the resolution of those matters, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, after making the requisite findings, will issue, deny, or appropriately condition the manufacturing license.

(e) *Initial decision—other proceedings not involving production or utilization facilities.* In proceedings not involving production or utilization facilities, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and on any matters designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties must be referred to the Director of Nuclear Material Safety and Safeguards, or the Director of the Office of Federal and State Materials and Environmental Management Programs, as appropriate. Depending on the resolution of those matters, the Director of Nuclear Material Safety and Safeguards or the Director of the Office of Federal and State Materials and Environmental Management Programs, as appropriate, after making the requisite findings, will issue, deny, revoke or appropriately condition the license, or take other action as necessary or appropriate.

(f) *Immediate effectiveness of certain decisions.* An initial decision directing the issuance or amendment of a limited work authorization under 10 CFR 50.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization under part 50 of this chapter, an operating license under part 50 of this chapter, a combined license under subpart C of part 52 of this chapter, a manufacturing license under subpart F of part 52 of this chapter, or a license under 10 CFR part 72 to store spent fuel in an independent spent fuel storage facility (ISFSI) or a monitored retrievable storage installation (MRS), an initial decision directing issuance of a license under part 61 of this chapter, or an initial decision under 10 CFR 52.103(g) that acceptance criteria in a combined license have been met, is immediately effective upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective.

(g)–(h) [Reserved]

(i) *Issuance of authorizations, permits, and licenses—production and utilization facilities.* The Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, shall issue a limited work authorization under 10 CFR 50.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization under part 50 of this chapter, an operating license under part 50 of this chapter, a combined license under subpart C of part 52 of this chapter, or a manufacturing license under subpart F of part 52 of this chapter within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the appropriate Director has made all findings necessary for issuance of the authorization, permit or license, not within the scope of the initial decision of the presiding officer; and

(2) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342, or the filing of a petition under § 2.206.

(j) *Issuance of finding on acceptance criteria under 10 CFR 52.103.* The Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation, as appropriate, shall make the finding under 10 CFR 52.103(g) that acceptance criteria in a combined license have been, or will be met, within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the appropriate Director has made the finding under § 52.103(g) that acceptance criteria have been, or will be met, for those acceptance criteria which are not within the scope of the initial decision of the presiding officer; and

(2) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342, or the filing of a petition under § 2.206.

(k) *Issuance of other licenses.* The Commission or the Director of Nuclear Material Safety and Safeguards, or the Director of the Office of Federal and State Materials and Environmental Management Programs, as appropriate, shall issue a license, including a license under 10 CFR part 72 to store spent fuel in either an independent spent fuel storage facility (ISFSI) located away from a reactor site or at a monitored retrievable storage installation (MRS), within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the appropriate Director has made all findings necessary for issuance of the license, not within the scope of the initial decision of the presiding officer; and

(2) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342; or the filing of a petition under § 2.206.

■ 21. In § 2.341, paragraph (a)(1) is revised to read as follows:

§ 2.341 Review of decisions and actions of a presiding officer.

(a)(1) Except for requests for review or appeals under § 2.311 or in a proceeding on the high-level radioactive waste repository (which are governed by § 2.1015), review of decisions and actions of a presiding officer are treated under this section, provided, however, that no party may request a further Commission review of a Commission determination to allow a period of interim operation under 10 CFR 52.103(c).

* * * * *

■ 22. In § 2.347, paragraph (a) is revised, and new paragraph (f)(5) is added to read as follows:

§ 2.347 Ex parte communications.

* * * * *

(a)(1) Interested persons outside the agency may not make or knowingly cause to be made to any Commission adjudicatory employee, any ex parte communication relevant to the merits of the proceeding.

(2) For purposes of this section, *merits of the proceeding* includes:

(i) A disputed issue;

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(ii) A matter which a presiding officer seeks to be referred to the Commission under 10 CFR 2.340(a); and

(iii) A matter for which the Commission has approved examination by the presiding officer under § 2.340(a).

* * * * *

(f) * * *

(5) Communications, in contested proceedings and uncontested mandatory proceeding, regarding an undisputed issue.

■ 23. In § 2.348, the introductory text of paragraph (a) is revised, and new paragraphs (d)(1)(iii), (d)(1)(iv), and (d)(3) are added to read as follows:

§ 2.348 Separation of functions.

(a) In any proceeding under this part, any NRC officer or employee engaged in the performance of any investigative or litigating function in the proceeding or in a factually related proceeding with respect to a disputed issue in that proceeding, may not participate in or advise a Commission adjudicatory employee about the initial or final decision with respect to that disputed issue, except—

* * * * *

(d) * * *

(1) * * *

(iii) A matter which a presiding officer seeks to be referred to the Commission under 10 CFR 2.340(a); and

(iv) A matter for which the Commission has approved examination by the presiding officer under § 2.340(a).

* * * * *

(3) Separation of functions does not apply to uncontested proceedings, or to an undisputed issue in contested initial licensing proceedings.

* * * * *

■ 24. 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:

* * * * *

■ 25. Subpart D is revised to read as follows:

Subpart D—Additional Procedures Applicable to Proceedings for the Issuance of Licenses To Construct and/or Operate Nuclear Power Plants of Identical Design at Multiple Sites

Sec.

2.400 Scope of subpart.
2.401 Notice of hearing on construction permit or combined license applications pursuant to appendix N of 10 CFR parts 50 or 52.
2.402 Separate hearings on separate issues; consolidation of proceedings.
2.403 Notice of proposed action on applications for operating licenses pursuant to appendix N of 10 CFR part 50.
2.404 Hearings on applications for operating licenses pursuant to appendix N of 10 CFR part 50.
2.405 Initial decisions in consolidated hearings.
2.406 Finality of decisions on separate issues.
2.407 Applicability of other sections.

§ 2.400 Scope of subpart.

This subpart describes procedures applicable to licensing proceedings which involve the consideration in hearings of a number of applications, filed by one or more applicants pursuant to appendix N of parts 50 or 52 of this chapter, for licenses to construct and/or operate nuclear power reactors of identical design to be located at multiple sites.

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

(a) In the case of applications pursuant to appendix N of part 50 of this chapter for construction permits for nuclear power reactors of the type described in § 50.22 of this chapter, or applications pursuant to appendix N of part 52 of this chapter for combined licenses, the Secretary will issue notices of hearing pursuant to § 2.104.

(b) The notice of hearing will also state the time and place of the hearings on any separate phase of the proceeding.

§ 2.402 Separate hearings on separate issues; consolidation of proceedings.

(a) In the case of applications under appendix N of part 50 of this chapter for construction permits for nuclear power reactors of a type described in 10 CFR 50.22, or applications pursuant to appendix N of part 52 of this chapter for combined licenses, the Commission or the presiding officer may order separate hearings on particular phases of the proceeding, such as matters related to the acceptability of the design of the reactor, in the context of the site parameters postulated for the design or environmental matters.

(b) If a separate hearing is held on a particular phase of the proceeding, the Commission or presiding officers of each affected proceeding may, under 10 CFR 2.317, consolidate for hearing on that phase two or more proceedings to consider common issues relating to the applications involved in the proceedings, if it finds that this action will be conducive to the proper dispatch of its business and to the ends of justice. In specifying the place of this consolidated hearing, due regard will be given to the convenience and necessity of the parties, petitioners for leave to intervene, or the attorneys or representatives of such persons, and the public interest.

§ 2.403 Notice of proposed action on applications for operating licenses pursuant to appendix N of 10 CFR part 50.

In the case of applications pursuant to appendix N of part 50 of this chapter for operating licenses for nuclear power reactors, if the Commission has not found that a hearing is in the public interest, the Commission, the Director of New Reactors, or the Director of Nuclear Reactor Regulation will, prior to acting thereon, cause to be published in the **Federal Register**, pursuant to § 2.105, a notice of proposed action with respect to each application as soon as practicable after the applications have been docketed.

§ 2.404 Hearings on applications for operating licenses pursuant to appendix N of 10 CFR part 50.

If a request for a hearing and/or petition for leave to intervene is filed within the time prescribed in the notice of proposed action on an application for an operating license pursuant to appendix N of part 50 of this chapter with respect to a specific reactor(s) at a specific site, and the Commission, the Chief Administrative Judge, or a presiding officer has issued a notice of hearing or other appropriate order, then the Commission, the Chief Administrative Judge, or the presiding officer may order separate hearings on particular phases of the proceeding and/or consolidate for hearing two or more proceedings in the manner described in § 2.402.

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§ 2.405 Initial decisions in consolidated hearings.

At the conclusion of a hearing held under this subpart, the presiding officer will render a partial initial decision on the common design. The partial initial decision on the common design may be appealed under § 2.341. If the proceedings have also been consolidated with respect to matters other than the common design under § 2.317(b), the presiding officer may issue a consolidated partial initial decision for those proceedings. No construction permit, full-power operating license, or combined license under part 52 of this chapter will be issued until an initial decision has been issued on all phases of the hearing and all issues under the Act and the National Environmental Policy Act of 1969 appropriate to the proceeding have been resolved.

§ 2.406 Finality of decisions on separate issues.

Notwithstanding any other provision of this chapter, in a proceeding conducted pursuant to this subpart and appendices N of parts 50 or 52 of this chapter, no matter which has been reserved for consideration in one phase of the hearing shall be considered at another phase of the hearing except on the basis of significant new information that substantially affects the conclusion(s) reached at the other phase or other good cause.

§ 2.407 Applicability of other sections.

The provisions of subparts A, C, G, L, and N of this part relating to construction permits, operating licenses, and combined licenses apply, respectively, to construction permits, operating licenses, and combined licenses subject to this subpart, except as may be qualified by the provisions of this subpart.

■ 26. 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.

■ 27. In § 2.501, the section heading, the introductory text of paragraph (a) and paragraph (b) are revised to read as follows:

§ 2.501 Notice of hearing on application under subpart F of 10 CFR part 52 for a license to manufacture nuclear power reactors.

(a) In the case of an application under subpart F of part 52 of this chapter for a license to manufacture nuclear power reactors of the type described in § 50.22 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the **Federal Register** at least 30 days before the date set for hearing in the notice.[1] The notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

* * * * *

(b) The notice of hearing shall comply with the requirements of § 2.104(f) of this chapter.

* * * * *

§ 2.502 [Removed]

■ 28. Remove and reserve § 2.502.

§ 2.503 [Removed]

■ 29. Remove and reserve § 2.503.

§ 2.504 [Removed]

■ 30. Remove and reserve § 2.504.

■ 31. Subpart F is revised to read as follows:

Subpart F—Additional Procedures Applicable to Early Partial Decisions on Site Suitability Issues in Connection With an Application for a Construction Permit or Combined License for Certain Utilization Facilities

Sec.

2.600 Scope of subpart.
2.601 Applicability of other sections.

Early Partial Decisions on Site Suitability—Construction Permit

2.602 Filing Fees.
2.603 Acceptance and docketing of application for early review of site suitability issues in a construction permit proceeding.
2.604 Notice of hearing on application for early review of site suitability issues in construction permit proceeding.
2.605 Additional considerations.
2.606 Partial decision on site suitability issues in construction permit proceeding.

Early Partial Decisions on Site Suitability—Combined License Under 10 CFR Part 52

2.621 Acceptance and docketing of application for early review of site suitability issues in a combined license proceeding.
2.623 Notice of hearing on application for early review of site suitability issues in combined license proceeding.
2.625 Additional considerations.
2.627 Partial decision on site suitability issues in combined license proceeding.
2.629 Finality of partial decision on site suitability issues in combined license proceeding.

§ 2.600 Scope of subpart.

This subpart prescribes procedures applicable to licensing proceedings which involve an early submittal of site suitability information in accordance with § 2.101(a–1) and (a–2), and a hearing and early partial decision on issues of site suitability, in connection with an application for a permit to construct a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility; or an application for a combined license under part 52 of this chapter for a nuclear power facility.

(a) The procedures in §§ 2.601 through 2.609 apply to all applications under this subpart.

(b) The procedures in §§ 2.611 through 2.619 apply to applications for a permit to construct a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility.

(c) The procedures in §§ 2.621 through 2.629 apply to applications for combined license under part 52 of this chapter for a nuclear power facility.

§ 2.601 Applicability of other sections.

The provisions of subparts A, C, G, L, and N relating to applications for construction permits and combined licenses, and proceedings thereon apply, respectively, to such applications and proceedings in accordance with this subpart, except as specifically provided otherwise by the provisions of this subpart.

Early Partial Decisions on Site Suitability—Construction Permit

§ 2.602 Filing fees.

Each application which contains a request for early review of site suitability issues under the procedures of this subpart shall be accompanied by any fee required by § 50.30(e) and part 170 of this chapter.

§ 2.603 Acceptance and docketing of application for early review of site suitability issues in a construction permit proceeding.

(a) Each part of an application for a construction permit submitted in accordance with § 2.101(a–1) of this part will be initially treated as a tendered

[1] The thirty-day (30) requirement of this paragraph is not applicable to a notice of the time and place of hearing published by the presiding officer after the notice of hearing described in this section has been published.

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application. If it is determined that any one of the parts as described in § 2.101(a–1) is incomplete and not acceptable for processing, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days.

(b)(1) The Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will accept for docketing part one of an application for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter, or is a testing facility where part one of the application as described in § 2.101(a–1) is complete. Part one of any application will not be considered complete unless it contains proposed findings as required by § 2.101(a–1)(1)(i) and unless it describes the applicant's site selection process, specifies the extent to which that process involves the consideration of alternative sites, explains the relationship between that process and the application for early review of site suitability issues, and briefly describes the applicant's long-range plans for ultimate development of the site. Upon assignment of a docket number, the procedures in § 2.101(a)(3) and (4) relating to formal docketing and the submission and distribution of additional copies of the application shall be followed.

(2) Additional parts of the application will be docketed upon a determination by the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, that they are complete.

(c) If part one of the application is docketed, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will cause to be published in the **Federal Register** and send to the Governor or other appropriate official of the State in which the site is located, a notice of docketing of the application which states the purpose of the application, states the location of the proposed site, states that a notice of hearing will be published, requests comments within 120 days or such other time as may be specified on the initiation or outcome of an early site review from Federal, State, and local agencies and interested persons.

§ 2.604 Notice of hearing on application for early review of site suitability issues in construction permit proceeding.

(a) Where an applicant for a construction permit requests an early review and hearing and an early partial decision on issues of site suitability pursuant to § 2.101(a–1), the provisions in the notice of hearing setting forth the matters of fact and law to be considered, as required by § 2.104, shall be modified so as to relate only to the site suitability issue or issues under review.

(b) After docketing of part two of the application, as provided in §§ 2.101(a–1) and 2.603, a supplementary notice of hearing will be published under § 2.104 with respect to the remaining unresolved issues in the proceeding within the scope of § 2.104. This supplementary notice of hearing will provide that any person whose interest may be affected by the proceeding and who desires to participate as a party in the resolution of the remaining issues shall file a petition for leave to intervene pursuant to § 2.309 within the time prescribed in the notice. This supplementary notice will also provide appropriate opportunities for participation by a representative of an interested State under § 2.315(c) and for limited appearances under § 2.315(a).

(c) Any person who was permitted to intervene as a party under the initial notice of hearing on site suitability issues and who was not dismissed or did not withdraw as a party may continue to participate as a party to the proceeding with respect to the remaining unresolved issues, provided that within the time prescribed for filing of petitions for leave to intervene in the supplementary notice of hearing, he or she files a notice of his intent to continue as a party, along with a supporting affidavit identifying the specific aspect or aspects of the subject matter of the proceeding as to which he or she wishes to continue to participate as a party and setting forth with particularity the basis for his contentions with regard to each aspect or aspects. A party who files a non-timely notice of intent to continue as a party may be dismissed from the proceeding, absent a determination that the party has made a substantial showing of good cause for failure to file on time, and with particular reference to the factors specified in §§ 2.309(c)(1)(i) through (iv) and 2.309(d). The notice will be ruled upon by the Commission or presiding officer designated to rule on petitions for leave to intervene.

(d) To the maximum extent practicable, the membership of any atomic safety and licensing board designated to preside in the proceeding on the remaining unresolved issues pursuant to the supplemental notice of hearing will be the same as the membership designated to preside in the initial notice of hearing on site suitability issues.

§ 2.605 Additional considerations.

(a) The Commission will not conduct more than one review of site suitability issues with regard to a particular site prior to filing and review of part two of the application described in § 2.101(a–1) of this part.

(b) The Commission, upon its own initiative, or upon the motion of any party to the proceeding filed at least 60 days prior to the date of the commencement of the evidentiary hearing on site suitability issues, may decline to initiate an early hearing or render an early partial decision on any issue or issues of site suitability:

(1) In cases where no partial decision on the relative merits of the proposed site and alternative sites under subpart A of part 51 of this chapter is requested, upon determination that there is a reasonable likelihood that further review would identify one or more preferable alternative sites and the partial decision on one or more site suitability issues would lead to an irreversible and irretrievable commitment of resources prior to the submittal of the remainder of the information required by § 50.30(f) of this chapter that would prejudice the later review and decision on such alternative sites; or

(2) In cases where it appears that an early partial decision on any issue or issues of site suitability would not be in the public interest considering:

(i) The degree of likelihood that any early findings on those issues would retain their validity in later reviews;

(ii) The objections, if any, of cognizant State or local government agencies to the conduct of an early review on those issues; and

(iii) The possible effect on the public interest and the parties of having an early, if not necessarily conclusive, resolution of those issues.

§ 2.606 Partial decision on site suitability issues in construction permit proceeding.

(a) The provisions of §§ 2.331, 2.339, 2.340, 2.343, 2.712, and 2.713 shall apply to any partial initial decision rendered in accordance with this subpart. A limited work authorization may not be issued under 10 CFR 50.10(e) and no construction permit may be issued without completion of the full review required by Section 102(2) of the National Environmental Policy Act of 1969, as amended, and

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subpart A of part 51 of this chapter. The authority of the Commission to review such a partial initial decision sua sponte, or to raise sua sponte an issue that has not been raised by the parties, will be exercised within the same time period as in the case of a full decision relating to the issuance of a construction permit.

(b)(1) A partial decision on one or more site suitability issues pursuant to the applicable provisions of part 50, subpart A of part 51, and part 100 of this chapter issued in accordance with this subpart shall:

(i) Clearly identify the site to which the partial decision applies; and

(ii) Indicate to what extent additional information may be needed and additional review may be required to enable the Commission to determine in accordance with the provisions of the Act and the applicable provisions of the regulations in this chapter whether a construction permit for a facility to be located on the site identified in the partial decision should be issued or denied.

(2) Following either the Commission (acting in the function of a presiding officer) issuance of a partial initial decision, or completion of Commission review of the partial initial decision of the Atomic Safety and Licensing Board, after hearing, on the site suitability issues, the partial decision shall remain in effect either for a period of 5 years or, where the applicant for the construction permit has made timely submittal of the information required to support the application as provided in § 2.101(a–1), until the proceeding for a permit to construct a facility on the site identified in the partial decision has been concluded,[3] unless the Commission or Atomic Safety and Licensing Board, upon its own initiative or upon motion by a party to the proceeding, finds that there exists significant new information that substantially affects the earlier conclusions and reopens the hearing record on site suitability issues. Upon good cause shown, the Commission may extend the 5-year period during which a partial decision shall remain in effect for a reasonable period of time not to exceed 1 year.

[3] The partial decision on site suitability issues shall be incorporated in the decision regarding issuance of the combined license to the extent that it serves as a basis for the decision on a specific site issue.

Early Partial Decisions on Site Suitability—Combined License Under 10 CFR Part 52

§ 2.621 Acceptance and docketing of application for early review of site suitability issues in a combined license proceeding.

(a) Each part of an application submitted in accordance with § 2.101(a–1) of this part will be initially treated as a tendered application. If it is determined that any one of the parts as described in § 2.101(a–1) is incomplete and not acceptable for processing, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days.

(b)(1) The Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will accept for docketing an application for a combined license for a nuclear power facility where part one of the application as described in § 2.101(a–1) is complete. Part one of any application will not be considered complete unless it contains proposed findings as required by § 2.101(a–1)(1)(i) and unless it describes the applicant's site selection process, specifies the extent to which that process involves the consideration of alternative sites, explains the relationship between that process and the application for early review of site suitability issues, and briefly describes the applicant's long-range plans for ultimate development of the site. Upon assignment of a docket number, the procedures in § 2.101(a)(3) and (4) relating to formal docketing and the submission and distribution of additional copies of the application shall be followed.

(2) Additional parts of the application will be docketed upon a determination by the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, that they are complete.

(c) If part one of the application is docketed, the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, will cause to be published in the **Federal Register** and send to the Governor or other appropriate official of the State in which the site is located, a notice of docketing of the application which states the purpose of the application, states the location of the proposed site, states that a notice of hearing will be published, requests comments within 120 days or such other time as may be specified on the initiation or outcome of an early site review from Federal, State, and local agencies and interested persons.

§ 2.623 Notice of hearing on application for early review of site suitability issues in combined license proceeding.

(a) Where an applicant for a combined license under part 52 of this chapter requests an early review and hearing and an early partial decision on issues of site suitability pursuant to § 2.101(a–2), the provisions in the notice of hearing setting forth the matters of fact and law to be considered, as required by § 2.104, shall be modified so as to relate only to the site suitability issue or issues under review. The notice will provide appropriate opportunities for participation by a representative of an interested State under § 2.315(c) and for limited appearances under § 2.315(a), limited however, to the issues of site suitability for which early review has been requested by the applicant.

(b) After docketing of part two of the application, as provided in §§ 2.101(a–1) and 2.603, a supplementary notice of hearing will be published under § 2.104 with respect to the remaining unresolved issues in the proceeding within the scope of § 2.104. This supplementary notice of hearing will provide that any person whose interest may be affected by the proceeding and who desires to participate as a party in the resolution of the remaining issues shall file a petition for leave to intervene pursuant to § 2.309 within the time prescribed in the notice. This supplementary notice will also provide appropriate opportunities for participation by a representative of an interested State under § 2.315(c) and for limited appearances under § 2.315(a).

(c) Any person who was permitted to intervene as a party under the initial notice of hearing on site suitability issues and who was not dismissed or did not withdraw as a party may continue to participate as a party to the proceeding without having to demonstrate standing under § 2.309(d), *provided, however,* that within the time prescribed for filing of petitions for leave to intervene in the supplementary notice of hearing, the party files a notice of intent to continue as a party. The notice must include the information required by § 2.309(f). A party who files a non-timely notice of intent to continue as a party may be dismissed from the proceeding, absent a determination that the party has made a substantial showing of good cause for failure to file on time, and with particular reference to the factors specified in §§ 2.309(c)(1)(i)

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through (iv) and 2.309(d). The notice will be ruled upon by the Commission or presiding officer designated to rule on petitions for leave to intervene.

(d) To the maximum extent practicable, the presiding officer (as applicable, the membership of the licensing board) designated to preside in the proceeding on the remaining unresolved issues pursuant to the supplemental notice of hearing will be the same as the presiding officer (as applicable, the membership of the licensing board) designated to preside in the initial notice of hearing on site suitability issues.

§ 2.625 Additional considerations.

(a) The Commission will not conduct more than one review of site suitability issues with regard to a particular site prior to filing and review of part two of the application described in § 2.101(a–1) of this part.

(b) The Commission, upon its own initiative, or upon the motion of any party to the proceeding filed at least 60 days prior to the date of the commencement of the evidentiary hearing on site suitability issues, may decline to initiate an early hearing or render an early partial decision on any issue or issues of site suitability:

(1) In cases where no partial decision on the relative merits of the proposed site and alternative sites under subpart A of part 51 is requested, upon determination that there is a reasonable likelihood that further review would identify one or more preferable alternative sites and the partial decision on one or more site suitability issues would lead to an irreversible and irretrievable commitment of resources prior to the submittal of the remainder of the information required by § 50.30(f) of this chapter that would prejudice the later review and decision on such alternative sites; or

(2) In cases where it appears that an early partial decision on any issue or issues of site suitability would not be in the public interest considering:

(i) The degree of likelihood that any early findings on those issues would retain their validity in later reviews;

(ii) The objections, if any, of cognizant State or local government agencies to the conduct of an early review on those issues; and

(iii) The possible effect on the public interest and the parties of having an early, if not necessarily conclusive, resolution of those issues.

§ 2.627 Partial decision on site suitability issues in combined license proceeding.

(a) The provisions of §§ 2.331, 2.339, 2.340(b), 2.343, 2.712, and 2.713 shall apply to any partial initial decision rendered in accordance with this subpart. Section 2.340(c) shall not apply to any partial initial decision rendered in accordance with this subpart. A limited work authorization may not be issued under 10 CFR 50.10(e) and no construction permit may be issued without completion of the full review required by Section 102(2) of the National Environmental Policy Act of 1969, as amended, and subpart A of part 51 of this chapter. The authority of the Commission to review such a partial initial decision sua sponte, or to raise sua sponte an issue that has not been raised by the parties, will be exercised within the same time period as in the case of a full decision relating to the issuance of a construction permit.

(b)(1) A partial decision on one or more site suitability issues pursuant to the applicable provisions of part 50, subpart A of part 51, and part 100 of this chapter issued in accordance with this subpart shall:

(i) Clearly identify the site to which the partial decision applies; and

(ii) Indicate to what extent additional information may be needed and additional review may be required to enable the Commission to determine in accordance with the provisions of the Act and the applicable provisions of the regulations in this chapter whether a construction permit for a facility to be located on the site identified in the partial decision should be issued or denied.

(2) Following either the Commission (acting in the function of a presiding officer) issuance of a partial initial decision, or completion of Commission review of the partial initial decision of the presiding officer, after hearing, on the site suitability issues, the partial decision shall remain in effect either for a period of 5 years or, where the applicant for the combined license has made timely submittal of the information required to support the application as provided in § 2.101(a–2), until the proceeding for a combined license on the site identified in the partial decision has been concluded, unless the Commission or presiding officer, upon its own initiative or upon motion by a party to the proceeding, finds that there exists significant new information that substantially affects the earlier conclusions and reopens the hearing record on site suitability issues. Upon good cause shown, the Commission may extend the 5-year period during which a partial decision shall remain in effect for a reasonable period of time not to exceed 1 year.

§ 2.629 Finality of partial decision on site suitability issues in a combined license proceeding.

(a) The partial decision on site suitability issues in a combined license proceeding shall be incorporated in the decision regarding issuance of a combined license. Except as provided in 10 CFR 2.758, in making the findings required for issuance of a combined license, the Commission shall treat as resolved those matters resolved in connection with the issuance of the partial decision on site suitability issues. If the Commission reaches an adverse decision, the application shall be denied without prejudice for resubmission, provided, however, that in determining whether the resubmitted application is complete and acceptable for docketing under § 2.101(a)(3), the Director of the Office of New Reactors or the Director of the Office of Nuclear Reactor Regulation, as appropriate, shall determine whether the resubmitted application addresses those matters identified as bases for denial of the original application.

(b) Notwithstanding any provision in 10 CFR 50.109, while a partial decision on site suitability is in effect under § 2.617(b)(2), the Commission may not modify, rescind, or impose new requirements with respect to matters within the scope of the site suitability decision, whether on its own motion, or in response to a request or petition from any person, unless the Commission determines that a modification to the original decision is necessary either for compliance with the Commission's regulations applicable and in effect at the time the partial decision was issued, or to assure adequate protection of the public health and safety or the common defense and security.

■ 32. Section 2.800 is revised to read as follows:

§ 2.800 Scope and applicability.

(a) This subpart governs the issuance, amendment, and repeal of regulations in which participation by interested persons is prescribed under Section 553 of title 5 of the U.S. Code.

(b) The procedures in §§ 2.804 through 2.810 apply to all rulemakings.

(c) The procedures in §§ 2.802 through 2.803 apply to all petitions for rulemaking except for initial applications for standard design certification rulemaking under subpart B of part 52 of this chapter, and subsequent petitions for amendment of an existing design certification rule filed by the original applicant for the design certification rule.

(d) The procedures in §§ 2.811 through 2.819, as supplemented by the

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provisions of subpart B of part 52, apply to standard design certification rulemaking.

■ 33. 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.

■ 34. In subpart H, §§ 2.811, 2.813, 2.815, 2.817 and 2.819 are added to read as follows:

§ 2.811 Filing of standard design certification application; required copies.

(a) *Serving of applications.* The signed original of an application for a standard design certification, including all amendments to the applications, must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; by facsimile; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by calling (301) 415–0439, by e-mail at *EIE@nrc.gov,* or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent.

(b) *Form of application.* Each original of an application and an amendment of an application must meet the requirements in § 2.813.

(c) *Capability to provide additional copies.* The applicant shall maintain the capability to generate additional copies of the general information and the safety analysis report, or part thereof or amendment thereto, for subsequent distribution in accordance with the written instructions of the Director, Office of New Reactors, the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate.

(d) *Public hearing copy.* In any hearing conducted under subpart O of this part for a design certification rulemaking, the applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding, and shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements of this part.

(e) *Pre-application consultation.* A prospective applicant for a standard design certification may consult with the NRC before filing an application by writing to the Director, Division of New Reactor Licensing, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, with respect to the subject matters listed in § 2.802(a)(1)(i) through (iii) of this chapter. A prospective petitioner also may telephone the Rulemaking, Directives, and Editing Branch on (301) 415–7163, or toll free on (800) 368–5642, or send e-mail to *NRCREP@nrc.gov* on these subject matters. In addition, a prospective applicant may confer informally with the NRC staff BEFORE filing an application for a standard design certification, and the limitations in § 2.802(a)(2) do not apply.

§ 2.813 Written communications.

(a) *General requirements.* All correspondence, reports, and other written communications from the applicant to the Nuclear Regulatory Commission concerning the regulations in this subpart, and parts 50, 52, and 100 of this chapter must be sent either by mail addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 7:30 a.m. and 4:15 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by calling (301) 415–0439, 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

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Federal Register a document withdrawing the application, if the notice of receipt of the application, an advance notice of proposed rulemaking, or a notice of proposed rulemaking for the standard design certification has been previously published in the **Federal Register**. If the notice of receipt, advance notice of proposed rulemaking or notice of proposed rulemaking was published on the NRC Web site, then the notice of action on the withdrawal will also be published on the NRC Web site.

(b) The withdrawal of an application does not authorize the removal of any document from the files of the Commission.

§ 2.819 Denial of application for failure to supply information.

(a) The Commission may deny an application for a standard design certification if an applicant fails to respond to a request for additional information within 30 days from the date of the request, or within such other time as may be specified.

(b) If the Commission denies an application because the applicant has failed to respond in a timely fashion to a request for additional information, the NRC will publish in the **Federal Register** a notice of denial and will notify the applicant with a simple statement of the grounds of denial. If a notice of receipt of application, advance notice of proposed rulemaking, or notice of proposed rulemaking for a standard design certification was published on the NRC Web site, then the notice of action on the denial will also be published on the NRC Web site.

■ 35. In § 2.1202, paragraph (a) is revised to read as follows:

§ 2.1202 Authority and role of NRC staff.

(a) During the pendency of any hearing under this subpart, consistent with the NRC staff's findings in its review of the application or matter which is the subject of the hearing and as authorized by law, the NRC staff is expected to issue its approval or denial of the application promptly, or take other appropriate action on the underlying regulatory matter for which a hearing was provided. When the NRC staff takes its action, it shall notify the presiding officer and the parties to the proceeding of its action. That notice must include the NRC staff's position on the matters in controversy before the presiding officer with respect to the staff action. The NRC staff's action on the matter is effective upon issuance by the staff, except in matters involving:

(1) An application to construct and/or operate a production or utilization facility (including an application for a limited work authorization under 10 CFR 50.12, or an application for a combined license under subpart C of 10 CFR part 52);

(2) An application for an early site permit under subpart A of 10 CFR part 52;

(3) An application for a manufacturing license under subpart F of 10 CFR part 52;

(4) An application for an amendment to a construction authorization for a high-level radioactive waste repository at a geologic repository operations area falling under either 10 CFR 60.32(c)(1) or 10 CFR part 63;

(5) An application for the construction and operation of an independent spent fuel storage installation (ISFSI) located at a site other than a reactor site or a monitored retrievable storage installation (MRS) under 10 CFR part 72; and

(6) Production or utilization facility licensing actions that involve significant hazards considerations as defined in 10 CFR 50.92.

* * * * *

§ 2.1211 [Removed]

■ 36. Section 2.1211 is removed.

PART 10—CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION OR AN EMPLOYMENT CLEARANCE

■ 37. 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.

■ 38. 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.

* * * * *

■ 39. 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

■ 40. 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).

■ 41. 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

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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.

■ 42. 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 of this chapter; 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.

■ 43. 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.

■ 44. In § 19.11, paragraph (c) is removed and reserved, and the introductory text of paragraph (a), 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) 415–7232, 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.

■ 45. Section 19.14 is revised to read as follows:

§ 19.14 Presence of representatives of licensees and regulated entities, and workers during inspections.

(a) Each licensee, applicant for a license, applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, applicant for an early site permit under subpart A of part 52 of this chapter, and applicant for a standard design certification under subpart B of part 52 of this chapter shall afford to the Commission at all

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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 phrases 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.

■ 46. Section 19.20 is revised to read as follows:

§ 19.20 Employee protection.

Employment discrimination by a licensee, a holder of a certificate of compliance issued under part 76 of this chapter or regulated entity subject to the requirements in this part as delineated in § 19.2(a), or a contractor or subcontractor of a licensee, a holder of a certificate of compliance issued under part 76 of this chapter, or regulated entity subject to the requirements in this part as delineated in § 19.2(a), against an employee for engaging in protected activities under this part or parts 30, 40, 50, 52, 54, 60, 61, 63, 70, 72, 76, or 150 of this chapter is prohibited.

■ 47. 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.

■ 48. 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

■ 49. 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).

■ 50. 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.

■ 51. 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.

* * * * *

■ 52. Section 20.1406 is revised to read as follows:

§ 20.1406 Minimization of contamination.

(a) Applicants for licenses, other than early site permits and manufacturing licenses under part 52 of this chapter and renewals, whose applications are submitted after August 20, 1997, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) Applicants for standard design certifications, standard design

approvals, and manufacturing licenses under part 52 of this chapter, whose applications are submitted after August 20, 1997, shall describe in the application how facility design will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

■ 53. 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/e-submittals.html,* by calling (301) 415–0439, 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

■ 54. 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).

■ 55. In § 21.2, paragraphs (a), (b), and (c) are revised to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to:

(1) Each individual, partnership, corporation, or other entity applying for or holding a license or permit under the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and each director and responsible officer of such a licensee;

(2) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation under parts 50 or 52 of this chapter, an ISFSI for the storage of spent fuel licensed under part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or part 72 of this chapter;

(3) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule under part 52 of this chapter; or supplying basic components with respect to that design certification, and each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, whose application for design certification has been granted under part 52 of this chapter, or who has supplied or is supplying basic components with respect to that design certification;

(4) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for or holding a standard design approval under part 52 of this chapter; or supplying basic components with respect to a standard design approval under part 52 of this chapter;

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 of this chapter or a combined license under part 52 of this chapter (for the period of construction until the date that the Commission makes the finding under § 52.103(g) of this chapter), or to manufacture a facility under part 52 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50 or part 52 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

* * * * *

■ 56. In § 21.3 the definitions of *basic component, defect, deviation,* and *substantial safety hazard* are revised to read as follows:

§ 21.3 Definitions.

* * * * *

Basic component. (1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe-shutdown condition; or

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(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

(2) When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

(i) The integrity of the reactor coolant pressure boundary;

(ii) The capability to shut down the reactor and maintain it in a safe-shutdown condition; or

(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

* * * * *

Defect means:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard;

(2) The installation, use, or operation of a basic component containing a defect as defined in this section;

(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter; or

(5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

Deviation means a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard 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.

* * * * *

■ 57. 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.

■ 58. In § 21.21 the introductory text of paragraph (a)(3), paragraph (a)(3)(i), and paragraphs (d)(1)(i), (d)(1)(ii), and (d)(4)(vi) are revised and paragraph (d)(4)(ix) is added to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) * * *

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraphs (a)(1) or (a)(2) of this section if the manufacture, construction, or operation of a facility or activity, a basic component supplied for such facility or activity, or the design certification or design approval under part 52 of this chapter—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission or standard design approval under part 52 of this chapter, relating to a substantial safety hazard, or

* * * * *

(d)(1) * * *

(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

(4) * * *

(vi) In the case of a basic component which contains a defect or fails to

comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

* * * * *

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

* * * * *

■ 59. In § 21.51 paragraphs (a)(4) and (a)(5) are added and paragraph (b) is revised to read as follows:

§ 21.51 Maintenance and inspection of records.

(a) * * *

(4) Applicants for standard design certification under subpart B of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.

(5) Applicants for or holders of a standard design approval under subpart E of part 52 of this chapter and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

■ 60. In § 21.61, paragraph (b) is revised to read as follows:

§ 21.61 Failure to notify.

* * * * *

(b) Any NRC licensee or applicant for a license (including an applicant for, or holder of, a permit), applicant for a design certification under part 52 of this chapter during the pendency of its application, applicant for a design certification after Commission adoption of a final design certification rule for that design, or applicant for or holder of a standard design approval under part 52 of this chapter subject to the regulations in this part who fails 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

■ 61. 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).

■ 62. The heading of part 25 is revised to read as set forth above.

■ 63. 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

■ 64. 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).

■ 65. 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.

* * * * *

■ 66. In § 26.10, paragraph (a) is revised to read as follows:

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§ 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;

* * * * *

■ 67. 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

■ 68. 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).

■ 69. 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.

* * * * *

■ 70. In § 50.10 the introductory text of paragraphs (b) and (c), and paragraphs (e)(1), (e)(2), and (e)(3) are revised to read as follows:

§ 50.10 License required.

* * * * *

(b) No person shall begin the construction of a production or utilization facility on a site on which the facility is to be operated until either a construction permit under this part, or a combined license under subpart C of part 52 of this chapter has been issued. As used in this paragraph, the term "construction" includes pouring the foundation for, or the installation of, any portion of the permanent facility on the site, but does not include:

* * * * *

(c) Notwithstanding the provisions of paragraph (b) of this section, and subject to paragraphs (d) and (e) of this section, no person shall effect commencement of construction of a production or utilization facility subject to the provisions of § 51.20(b) of this chapter on a site on which the facility is to be operated until an early site permit, construction permit, or combined license has been issued. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation or other substantial action that would adversely affect the environment of a site, but does not include:

* * * * *

(e)(1) The Director of Nuclear Reactor Regulation may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b)(2) or (3), or § 50.22 or is a testing facility, or an applicant for a combined license to conduct the following activities:

(i) Preparation of the site for construction of the facility (including activities as clearing, grading, construction of temporary access roads and borrow areas);

(ii) Installation of temporary construction support facilities (including items such as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings);

(iii) Excavation for facility structures;

(iv) Construction of service facilities (including facilities such as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines, and sanitary sewerage treatment facilities); and

(v) The construction of structures, systems and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

(2) No authorization shall be granted unless the staff has completed a final environmental impact statement on the issuance of the construction permit or combined license as required by subpart A of part 51 of this chapter. An authorization shall be granted only after the presiding officer in the proceeding on the construction permit or combined license application:

(i) Has made all the findings required by §§ 51.104(b), 51.105, and 51.107 of this chapter to be made before issuance of the construction permit, or combined license for the facility; and

(ii) Has determined that, based upon the available information and review to date, there is reasonable assurance that the proposed site is a suitable location for a reactor of the general size and type proposed from the standpoint of radiological health and safety considerations under the Act and regulations issued by the Commission.

(3)(i) The Director of New Reactors or the Director of Nuclear Reactor

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Regulation, as appropriate, may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b)(2) or (3), or § 50.22 or is a testing facility, or an applicant for a combined license to conduct, in addition to the activities described in paragraph (e)(1) of this section, the installation of structural foundations, including any necessary subsurface preparation, for structures, systems, and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

(ii) Such an authorization, which may be combined with the authorization described in paragraph (e)(1) of this section, or may be granted at a later time, shall be granted only after the presiding officer in the proceeding on the construction permit or combined license application has, in addition to making the findings and determinations required by paragraph (e)(2) of this section, determined that there are no unresolved safety issues relating to the additional activities that may be authorized under this paragraph that would constitute good cause for withholding authorization.

* * * * *

■ 71. 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.

■ 72. The undesignated center heading before § 50.30 is revised to read as follows:

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

■ 73. In § 50.30, the section heading and paragraphs (a)(1), (a)(3), (a)(5), (a)(6), (b), (e), and (f) are revised to read as follows:

§ 50.30 Filing of application; oath or affirmation.

(a) * * *

(1) Each filing of an application for a standard design approval or license to construct and/or operate, or manufacture, a production or utilization facility (including an early site permit, combined license, and manufacturing license under part 52 of this chapter), and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission in accordance with § 50.4 or § 52.3 of this chapter, as applicable.

* * * * *

(3) Each applicant for a construction permit under this part, or an early site permit, combined license, or manufacturing license under part 52 of this chapter, shall, upon notification by the Atomic Safety and Licensing Board appointed to conduct the public hearing required by the Atomic Energy Act, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by the Atomic Safety and Licensing Board. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the U.S. Nuclear Regulatory Commission as specified in § 50.4 or § 52.3 of this chapter, as applicable.

* * * * *

(5) At the time of filing an application, the Commission will make available at the NRC Web site, *http://www.nrc.gov*, a copy of the application, subsequent amendments, and other records pertinent to the matter which is the subject of the application for public inspection and copying.

(6) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 50.4 or § 52.3 of this chapter, as applicable, to enable the Director, Office of New Reactors, or the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate, to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation.* Each application for a standard design approval or license, including, whenever appropriate, a construction permit or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

* * * * *

(e) *Filing Fees.* Each application for a standard design approval or production or utilization facility license, including, whenever appropriate, a construction permit or early site permit, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in part 170 of this chapter. No fee will be required to accompany an application for renewal, amendment, or termination of a construction permit, operating license, combined license, or manufacturing license, except as provided in § 170.21 of this chapter.

(f) *Environmental report.* An application for a construction permit, operating license, early site permit, combined license, or manufacturing license for a nuclear power reactor, testing facility, fuel reprocessing plant, or other production or utilization facility whose construction or operation may be determined by the Commission to have a significant impact in the environment, shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

■ 74. In § 50.33, paragraphs (f)(3) and (f)(4) are redesignated as (f)(4)and (f)(5), respectively, and are revised, a new paragraph (f)(3) is added, and paragraphs (g), (h), and (k)(1) are revised to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(f) * * *

(3) If the application is for a combined license under subpart C of part 52 of this chapter, the applicant shall submit the information described in paragraphs (f)(1) and (f)(2) of this section.

(4) Each application for a construction permit, operating license, or combined license submitted by a newly-formed entity organized for the primary purpose of constructing and/or operating a facility must also include information showing:

(i) The legal and financial relationships it has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(5) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(g) If the application is for an operating license or combined license for a nuclear power reactor, or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, the applicant shall submit radiological emergency response plans of State and local governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),[4] as well as the plans of State governments wholly or partially within the ingestion pathway EPZ.[5] If the application is for an early site permit that, under 10 CFR 52.17(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must meet the requirements of this paragraph. Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ shall consist of an area about 50 miles (80 km) in radius. The exact size and configuration of the EPZs surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 MW thermal. The plans for the ingestion pathway shall focus on such actions as are appropriate to protect the food ingestion pathway.

(h) If the applicant, other than an applicant for a combined license, proposes to construct or alter a production or utilization facility, the application shall state the earliest and latest dates for completion of the construction or alteration.

* * * * *

(k)(1) For an application for an operating license or combined license for a production or utilization facility, information in the form of a report, as described in § 50.75, indicating how reasonable assurance will be provided that funds will be available to decommission the facility.

* * * * *

■ 75. In § 50.34, the section heading, the introductory text of paragraph (a)(1), paragraphs (a)(1)(ii)(E) and (a)(12), the introductory text of paragraph (b), paragraphs (b)(10) and (b)(11), and paragraphs (c), (d), and (e), the introductory text of paragraphs (f) and(f)(1), and paragraphs (g), and (h)(1)(ii) are revised to read as follows:

§ 50.34 Contents of construction permit and operating license applications; technical information.

(a) * * *

(1) Stationary power reactor applicants for a construction permit who apply on or after January 10, 1997, shall comply with paragraph (a)(1)(ii) of this section. All other applicants for a construction permit shall comply with paragraph (a)(1)(i) of this section.

* * * * *

(ii) * * *

(E) With respect to operation at the projected initial power level, the applicant is required to submit information prescribed in paragraphs (a)(2) through (a)(8) of this section, as well as the information required by paragraph (a)(1)(i) of this section, in support of the application for a construction permit.

* * * * *

(12) On or after January 10, 1997, stationary power reactor applicants who apply for a construction permit, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria in appendix S to this part.

(b) *Final safety analysis report.* Each application for an operating license shall include a final safety analysis report. The final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and shall include the following:

* * * * *

(10) On or after January 10, 1997, stationary power reactor applicants who apply for an operating license, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria of appendix S to this part. However, for those operating license applicants and holders whose construction permit was issued before January 10, 1997, the earthquake engineering criteria in Section VI of appendix A to part 100 of this chapter continues to apply.

(11) On or after January 10, 1997, stationary power reactor applicants who apply for an operating license, shall provide a description and safety assessment of the site and of the facility as in § 50.34(a)(1)(ii). However, for either an operating license applicant or holder whose construction permit was issued before January 10, 1997, the reactor site criteria in part 100 of this chapter and the seismic and geologic siting criteria in appendix A to part 100 of this chapter continues to apply.

(c) *Physical Security Plan.* Each application for an operating license for a production or utilization facility must include a physical security plan. The plan must describe how the applicant will meet the requirements of part 73 of this chapter (and part 11 of this chapter, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(d) *Safeguards contingency plan.* Each application for an operating license for a production or utilization facility that will be subject to §§ 73.50, 73.55, or § 73.60 of this chapter, must include a licensee safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for such a license shall include the first four categories of information contained in the applicant's safeguards contingency plan. (The first four categories of information as set forth in appendix C to 10 CFR part 73

[4] Emergency 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.

[5] If 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.

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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 manufacturing license will require the plant design to be updated no later than 5 years after its approval. Paragraphs (f)(1)(xii), (2)(ix), and (3)(v) of this section, pertaining to hydrogen control measures, must be met by all applicants covered by this regulation. However, the Commission may decide to impose additional requirements and the issue of whether compliance with these provisions, together with 10 CFR 50.44 and criterion 50 of appendix A to 10 CFR part 50, is sufficient for issuance of that manufacturing license which may be considered in the manufacturing license proceeding. In addition, each applicant for a design certification, design approval, combined license, or manufacturing license under part 52 of this chapter shall demonstrate compliance with the technically relevant portions of the requirements in paragraphs (f)(1) through (3) of this section, except for paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v).

(1) To satisfy the following requirements, the application shall provide sufficient information to describe the nature of the studies, how they are to be conducted, estimated submittal dates, and a program to ensure that the results of these studies are factored into the final design of the facility. For licensees identified in the introduction to paragraph (f) of this section, all studies must be completed no later than 2 years following the issuance of the construction permit or manufacturing license.[10] For all other applicants, the studies must be submitted as part of the final safety analysis report.

* * * * *

(g) *Combustible gas control.* All applicants for a reactor construction permit or operating license whose application is submitted after October 16, 2003, shall include the analyses, and the descriptions of the equipment and systems required by § 50.44 as a part of their application.

(h) * * *

(1) * * *

(ii) Applications for light-water-cooled nuclear power plant construction permits docketed after May 17, 1982, shall include an evaluation of the facility against the SRP in effect on May 17, 1982, or the SRP revision in effect six months before the docket date of the application, whichever is later.

* * * * *

■ 76. 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:

[9] A 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.

[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.

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(1) A description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) The information required in paragraph (b)(2) of this section.

(e) Each application for a design approval, a design certification, or a manufacturing license under part 52 of this chapter shall include:

(1) A description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and

(2) The information required in paragraph (b)(2) of this section.

■ 77. In § 50.36, paragraphs (c), (d), and (e) are redesignated as paragraphs (d), (e), and (f), respectively, and a new paragraph (c) is added to read as follows:

§ 50.36 Technical specifications.

* * * * *

(c) Each applicant for a design certification or manufacturing license under part 52 of this chapter shall include in its application proposed generic technical specifications in accordance with the requirements of this section for the portion of the plant that is within the scope of the design certification or manufacturing license application.

* * * * *

■ 78. In § 50.36a, paragraph (a) is revised to read as follows:

§ 50.36a Technical specifications on effluents from nuclear power reactors.

(a) To keep releases of radioactive materials to unrestricted areas during normal conditions, including expected occurrences, as low as is reasonably achievable, each licensee of a nuclear power reactor and each applicant for a design certification or a manufacturing license will include technical specifications that, in addition to requiring compliance with applicable provisions of § 20.1301 of this chapter, require that:

(1) Operating procedures developed pursuant to § 50.34a(c) for the control of effluents be established and followed and that the radioactive waste system, pursuant to § 50.34a, be maintained and used. The licensee shall retain the operating procedures in effect as a record until the Commission terminates the license and shall retain each superseded revision of the procedures for 3 years from the date it was superseded.

(2) Each holder of an operating license, and each holder of a combined license after the Commission has made the finding under § 52.103(g) of this chapter, shall submit a report to the Commission annually that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous 12 months, including any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases. The report must be submitted as specified in § 50.4, and the time between submission of the reports must be no longer than 12 months. If quantities of radioactive materials released during the reporting period are significantly above design objectives, the report must cover this specifically. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

* * * * *

■ 79. Section 50.36b is revised to read as follows:

§ 50.36b Environmental conditions.

(a) Each construction permit under this part, each early site permit under part 52 of this chapter, and each combined license under part 52 of this chapter may include conditions to protect the environment during construction. These conditions are to be set out in an attachment to the permit or license, which is incorporated in and made a part of the permit or license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 51.50 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(b) Each license authorizing operation of a production or utilization facility, including a combined license under part 52 of this chapter, and each license for a nuclear power reactor facility for which the certification of permanent cessation of operations required under § 50.82(a)(1) or § 52.110(a) of this chapter has been submitted, which is of a type described in § 50.21(b)(2) or (3) or § 50.22 or is a testing facility, may include conditions to protect the environment during operation and decommissioning. These conditions are to be set out in an attachment to the license which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted pursuant to §§ 51.50 and 51.53 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

■ 80. Section 50.37 is revised to read as follows:

§ 50.37 Agreement limiting access to Classified Information.

As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license, construction permit, early site permit, or standard design approval, or before the Commission has adopted a final standard design certification rule under part 52 of this chapter, the applicant shall agree in writing that it will not permit any individual to have access to any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license, or construction permit, or standard design approval.

■ 81. The undesignated center heading before § 50.40 is revised to read as follows:

Standards for Licenses, Certifications, and Regulatory Approvals

■ 82. 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

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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.

■ 83. 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.

■ 84. Section 50.45 is revised to read as follows:

§ 50.45 Standards for construction permits, operating licenses, and combined licenses.

(a) An applicant for an operating license or an amendment of an operating license who proposes to construct or alter a production or utilization facility will be initially granted a construction permit if the application is in conformity with and acceptable under the criteria of §§ 50.31 through 50.38, and the standards of §§ 50.40 through 50.43, as applicable.

(b) A holder of a combined license who proposes, after the Commission makes the finding under § 52.103(g) of this chapter, to alter the licensed facility will be initially granted a construction permit if the application is in conformity with and acceptable under the criteria of §§ 50.30 through 50.33, § 50.34(f), §§ 50.34a through 50.38, the standards of §§ 50.40 through 50.43, as applicable, and §§ 52.79 and 52.80 of this chapter.

■ 85. 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

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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.

* * * * *

■ 86. In § 50.47, paragraph (a)(1) is revised and paragraph (e) is added to read as follows:

§ 50.47 Emergency plans.

(a)(1)(i) Except as provided in paragraph (d) of this section, no initial operating license for a nuclear power reactor will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed nuclear power reactor operating license.

(ii) No initial combined license under part 52 of this chapter will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed combined license.

(iii) If an application for an early site permit under subpart A of part 52 of this chapter includes complete and integrated emergency plans under 10 CFR 52.17(b)(2)(ii), no early site permit will be issued unless a finding is made by the NRC that the emergency plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(iv) If an application for an early site permit proposes major features of the emergency plans under 10 CFR 52.17(b)(2)(i), no early site permit will be issued unless a finding is made by the NRC that the major features are acceptable in accordance with the applicable standards of 10 CFR 50.47 and 10 CFR part 50, appendix E, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

(e) Notwithstanding the requirements of paragraph (b) of this section and the provisions of § 52.103 of this chapter, a holder of a combined license under part 52 of this chapter may not load fuel or operate except as provided in accordance with appendix E to part 50 and § 50.54(gg).

■ 87. In § 50.48, the introductory text of paragraph (a)(1) is revised and paragraph (a)(4) is added 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:

* * * * *

(a)(4) Each applicant for a design approval, design certification, or manufacturing license under part 52 of this chapter must have a description and analysis of the fire protection design features for the standard plant necessary to demonstrate compliance with Criterion 3 of appendix A to this part.

* * * * *

■ 88. In § 50.49, paragraph (a) is revised to read as follows:

§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

(a) Each holder of or an applicant for an operating license issued under this part, or a combined license or manufacturing license issued under part 52 of this chapter, other than a nuclear power plant for which the certifications required under § 50.82(a)(1) or § 52.110(a)(1) of this chapter have been submitted, shall establish a program for qualifying the electric equipment defined in paragraph (b) of this section. For a manufacturing license, only electric equipment defined in paragraph (b) which is within the scope of the manufactured reactor must be included in the program.

* * * * *

■ 89. In § 50.54, the introductory text, and paragraphs (a)(1), (i–1), (o), (p), and (q) are revised and paragraph (gg) is added to read as follows:

§ 50.54 Conditions of licenses.

The following paragraphs with the exception of paragraphs (r) and (gg) of this section are conditions in every nuclear power reactor operating license issued under this part. The following paragraphs with the exception of paragraph (r), (s), and (u) of this section are conditions in every combined license issued under part 52 of this chapter, provided, however, that paragraphs (i), (i–1), (j), (k), (l), (m), (n), (w), (x), (y), and (z) of this section are only applicable after the Commission makes the finding under § 52.103(g) of this chapter.

(a)(1) Each nuclear power plant or fuel reprocessing plant licensee subject to the quality assurance criteria in appendix B of this part shall implement, under § 50.34(b)(6)(ii) or § 52.79 of this chapter, the quality assurance program described or referenced in the safety analysis report, including changes to that report. However, a holder of a combined license under part 52 of this chapter shall implement the quality assurance program described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for the initial loading of fuel.

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(i–1) Within 3 months after either the issuance of an operating license or the date that the Commission makes the finding under § 52.103(g) of this chapter for a combined license, as applicable, the licensee shall have in effect an operator requalification program. The operator requalification program must, as a minimum, meet the requirements of § 55.59(c) of this chapter. Notwithstanding the provisions of § 50.59, the licensee may not, except as specifically authorized by the Commission decrease the scope of an approved operator requalification program.

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(o) Primary reactor containments for water cooled power reactors, other than facilities for which the certifications required under §§ 50.82(a)(1) or 52.110(a)(1) of this chapter have been submitted, shall be subject to the requirements set forth in appendix J to this part.

(p)(1) The licensee shall prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for effecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may make no change which would decrease the effectiveness of a security plan, or guard training and

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