
Comment Summary Report

Final Rule for 10 CFR Part 52 Licenses, Certifications, and Approvals for Nuclear Power Plants

October 11, 2006

**Division of New Reactor Licensing
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001**



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Appendix A: Comment Numbers, Commenter Names and Organizations, and Issues
Commented On

Acronyms and Abbreviations

| | |
|--------|---|
| ACRS | Advisory Committee on Reactor Safeguards |
| AEA | Atomic Energy Act |
| APA | Administrative Procedure Act |
| ASME | American Society of Mechanical Engineers |
| CEQ | Council on Environmental Quality |
| CFR | Code of Federal Regulations |
| COL | combined license |
| COLA | combined license application |
| CP | construction permit |
| CWA | Clean Water Act |
| CZMA | Coastal Zone Management Act |
| DC | design certification |
| DCD | design control document |
| DCR | design certification rule |
| EIS | environmental impact statement |
| EP | emergency plans |
| ERA | Energy Reorganization Act |
| ESP | early site permit |
| FDA | final design approval |
| FR | <i>Federal Register</i> |
| FSAR | final safety analysis report |
| GSI | generic safety issues |
| ITAAC | inspections, tests, analyses, and acceptance criteria |
| LWR | light water reactor |
| LWAs | limited work authorizations |
| ML | manufacturing license |
| NEI | Nuclear Energy Institute |
| NEPA | National Environmental Policy Act |
| NOPR | Notice of Proposed Rulemaking |
| NRC | Nuclear Regulatory Commission |
| PPE | plant parameter envelope |
| PRA | probabilistic risk assessment |
| QA | quality assurance |
| SAMDAs | severe accident design mitigation alternatives |
| SDA | standard design approval |
| SRM | staff requirements memorandum |
| SRP | standard review plan |
| SSAR | site safety analysis report |
| SSCs | structures, systems, and components |
| U.S. | United States of America |
| USC | U.S. Code |
| X/Q | atmospheric dispersion factors |

Preface

This document summarizes comments the U.S. Nuclear Regulatory Commission (NRC) received in response to publication of a proposed rule on Licenses, Certifications, and Approvals for Nuclear Power Plants in the *Federal Register* (FR) on March 13, 2006 (71 FR 12782). The notice requested comments on 15 specific questions and on NRC's proposed revisions to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52 and on proposed changes throughout the Commission's regulations to clarify the applicability of various requirements to each of the processes in Part 52 (*i.e.*, early site permits, standard design approvals, standard design certifications, combined licenses, and manufacturing licenses). The NRC received 19 comment letters during the public comment period which ended on May 30, 2006. The NRC also received 3 comment letters submitted well after the public comment period closed. Although the NRC did not specifically address the 3 late comment letters, the majority of the comments in these 3 letters were already addressed by other commenters and, therefore, are discussed in this report. For each comment letter, the NRC assigned a sequential number, and then also assigned numbers to topics or issues within the document. This report is generally structured to match the outline of the final rule Federal Register Notice.

Appendix A to this report contains a table that identifies the comment number, commenter name and organization, and the issues—by summary section number—on which they commented.

Summarized Comments Received By Issue

- 1 Background (Development of 2003 & 2005 Proposed Rules)
- 2 Overview of Public Comments (summary & pointers to other sections)

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

Comments 007-11, 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017:¹ Several commenters identified four types of changes in the proposed rule: (1) changes to Part 52 to copy some requirements and contain references to other requirements from Part 50 and other regulations, (2) changes to Part 50 and other regulations to contain references to Part 52, (3) changes to Part 52 that would delete the existing provisions in 10 CFR 52.83 and modify other regulations such as 10 CFR 52.81 to delete the statement that Part 50 and other regulations apply to the extent “technically relevant,” and (4) 10 CFR 52.0, which contains general provisions regarding the applicability of other parts. The commenters stated that they understood the changes were not intended to impose new requirements on Part 52 applicants, but instead to clarify which requirements were applicable to Part 52 applicants (*i.e.*, the changes were not meant to be substantive). The commenters stated that they nevertheless had a number of concerns with the proposed rule. They noted proposed § 52.0(b) stated that unless otherwise specifically provided for, the regulations in 10 CFR Chapter 1 would apply to a holder of, or applicant for, an approval, certification, permit, or license. The commenters believed this sentence was “unnecessary” and conflicted with other provisions in § 52.0(b), which stated that only the “applicable” provisions applied. The commenters also expressed concern that the NRC may have missed applicable requirements or provisions (*e.g.*, past mistakes in Part 171 that were corrected in the Notice of Proposed Rulemaking). The commenters stated that in order to account for such inadvertent oversights by the NRC and reviewers, it was “critical” that Part 52 contain language similar to that currently in §§ 52.81 and 52.83 (*i.e.*, “applicable as technically relevant” language to encompass regulations meant to apply to Part 52 applicants that are not specifically addressed in the proposed rule). The commenters expressed the belief that no downside existed to retaining this existing language.

NRC Response: While the Commission understands the concerns of the commenters, the Commission declines to adopt the solution presented by one of the commenters. As that commenter recognizes, the Commission's approach in the proposed rule was to: (i) adopt regulatory language that made clear that all “applicable” Commission requirements throughout 10 CFR Chapter 1 apply to holders or applicants for Part 52 licenses and approvals (first sentence of § 52.0(b)), and to the Part 52 licenses and approvals themselves (second sentence of § 52.0(b)); and (ii) conform the language of the Commission's regulatory language, wherever necessary, to explicitly delineate what requirements are “applicable” to the licensees, applicants, licenses and approvals. The commenter' correctly adduces the potential weakness

¹Commenters 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017 all fully endorsed and supported the Nuclear Energy Institute's (NEI's) comments of May 30, 2006. Therefore, all of these commenters are included in each of NEI's May 30, 2006 comments (comment number 007). For simplicity, these comment numbers are not repeated in this document for each comment.

in this approach, viz., that there may be an inadvertent failure by the Commission to identify a necessary conforming change in the one or more of the Commission's regulations.

However, in the Commission's view, the proposed solution presented by one of the commenters presents more significant problems with respect to regulatory certainty and stability. If the Commission were to adopt the commenter's suggestion of inserting the phrase, "technically relevant," into §§ 52.0, 52.58, 52.81, 52.139, and 52.159, this would re-introduce to some extent the problem, present in the original Part 52 rule, of determining whether any particular Commission requirement in 10 CFR Chapter 1 is, in fact, "technically relevant" to any particular licensee, applicant, license or approval. This could lead to unnecessary disputes between an applicant and the NRC whether a particular NRC requirement, silent on its face as to its applicability to that applicant, nonetheless is "technically applicable" and therefore must be complied with. A licensee's failure to comply with what NRC regards as "technically relevant" requirements would be the focus of enforcement. Finally, interested persons in a licensing proceeding would be able to request a hearing on the basis that a particular "technically relevant" regulation was neither addressed in the application nor otherwise complied with by the applicant.

Inasmuch as the commenter's proposed suggestion would not effectively address the earlier-identified concerns on the ambiguity of the term, "technically relevant," the Commission declines to adopt the commenters' proposed changes in the final Part 52 rule. The Commission believes that any inadvertent failure by the Commission to properly delineate the applicability of a provision in the Commission's regulations can be dealt with on a case-by-case basis through rulemaking or Commission order (e.g., under the provisions of 10 CFR 2.335).

4 Responses to Specific Requests for Comments (Questions A-O)

4.1 Question 1: General Provisions - Create new Subpart in Part 50 – not update Part 52

Comment 007-88: Commenters stated the clarity of the regulations would not be enhanced by moving provisions from Part 52 to Subpart 50. The commenters argued that in addition to not eliminating existing confusion, such a content shift would create new confusion because current documents referencing Part 52 would become "obsolete."

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

4.2 Question 2: EP Major Features - Revise options for proposing major features of emergency plans in ESP process

Comment 007-89: Several commenters suggested the current process for addressing major features of emergency plans (EP) in the early site permit (ESP) be retained without modification. Commenters expressed a fear that the loss of this option would result in a loss of flexibility to achieve “finality” without producing a comprehensive EP. Commenters identified a need to clarify the definition of “major features” of the EP to make it less restrictive. Commenters [believed that the approved major features were acceptable elements of a “complete and integrated emergency plan that would be considered later.” Commenters believed the information should not be reviewed again during the COL process, which would instead focus on (1) the integration of these major features with information necessary to support the “reasonable assurance finding”, and (2) the updating of EP information required by § 52.39 (b). Commenters referenced comments made in excerpt 007-16.

NRC Response: Based on commenters’ feedback, the NRC has decided to retain the current process for addressing major features of emergency plans in an ESP without modification. The NRC agrees that it should clarify the definition of major features and has done so by adding the definition suggested by the commenters to § 52.1 in the final rule.

4.3 Question 3: Appendix Q - Retain the Early Site Review Process

Comments 007-43, 007-90: Commenters expressed concern about the loss of flexibility to assess site suitability that would result from the deletion of Appendix Q. Commenters believed that Appendix Q (in conjunction with Subpart F of 10 CFR Part 2) was important for allowing “critical path issues” to be reviewed prior to submission of a Combined License Application (COLA) in instances where prior completion of an ESP was not feasible. Commenters argued for the efficiency of Appendix Q and Subpart F because only applicant-selected issues would be reviewed during these processes. Commenters recommended changes be made to specifically allow ESP and COL applicants to reference an early site review conducted in accordance with Appendix Q or Subpart F. The commenters stated that the NRC should not delete the option for a Part 52 applicant to reference a review performed under Appendix Q for reasons mentioned in excerpt 007-90 (summary Sections 4.3, 5.3, and 4.4.22).

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

In response to commenters concerns, the NRC has decided not to remove Appendix Q from Part 50 or Part 52 in the final rule. Appendix Q has been included in Part 52 in the final rule and conforming changes have been made to make it available for use by prospective early site

permits and combined license applicants. Such applicants will have the same option for early resolution of site suitability issues as is currently available to construction permit applicants. This will provide early site permit and combined license applicants with additional flexibility to seek early resolution of issues.

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

4.4 Question 4: ML Finality - Provide future option for NRC approval of ITAAC for manufacturing

Comment 007-91: Commenters requested that applicants for manufacturing licenses be allowed, but not required, to use inspections, tests, analyses, and acceptance criteria (ITAAC) to ensure that an “as-manufactured plant conforms to the important design characteristics specified in the application for the manufacturing license.”

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

4.5 Question 5: 50/52 Segregation - Remove provisions allowing a construction permit applicant to reference an ESP or DC

Comment 007-92: Commenters stated the deletion of provisions allowing a construction permit applicant to reference an ESP or DC was ill-advised given the untested nature of the COL process and the resulting need to retain “regulatory flexibility” to deal with unexpected issues. As a contingency plan to buffer against difficulties with COL process, the commenters proposed the addition of a provision in Part 50 to specify that a construction permit applicant could reference a DC without the inclusion of ITAAC. The commenters suggested that in these instances, “the operating license proceeding would need to find under 10 CFR 50.57(a)(1) that construction of the facility has been substantially completed, in conformity with the construction

permit and the application as amended, the provisions of the Act, and the rules and regulations of the Commission.” Commenters stated that standard design should be final and not open to review in the construction permit and operating licenses proceeding. Commenters requested a construction permit applicant be able to reference an ESP in the same way as would a COL applicant.

NRC Response: Based on commenters response to this question and further consideration of the issue, the NRC has decided not to make any changes in the final rule to delete provisions allowing a construction permit applicant to reference an early site permit or a design certification. The NRC has also decided not to add any additional provisions to Part 50 or Part 52 to address a construction permit applicant’s ability to reference either a design certification or an early site permit. The NRC believes it is unlikely that such a construction permit application will be submitted and the NRC will handle any such applications on a case-by-case basis. If such an application were submitted, there are many process issues that would need to be carefully considered and would need to be discussed with the applicant.

4.6 Question 6: Fuel Load Date - Require notification of NRC of the scheduled date for fuel loading

Comment 007-93: Commenters stated that a rule change was unnecessary to address the NRC notification because a guidance from the NRC would be sufficient. Commenters suggested that following the initial notification, a licensee should be required to submit a follow-up 30-day notification only if the schedule in the prior notification had changed.

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

4.7 Question 7: Op Programs - Additional required operational programs that should be described in a COL

Comment 007-94: Commenters believed that requirements for operational programs were sufficient as proposed, and that no additional operational programs needed to be described in the COL application.

NRC Response: The NRC does not agree that no additional operational programs need to be described in a COL application. During the preparation of the final rule, the NRC discovered that several of the operational programs listed in SECY-05-0197 were not addressed in proposed § 52.79. To ensure the list of requirements for the contents of applications is complete, the NRC is adding several new provisions to address operational programs in the final rule. Specifically, the NRC is adding requirements to § 52.79 for COL applicants to include a description of: (1) the process and effluent monitoring and sampling program required by Appendix I to 10 CFR Part 50 [§ 52.79(a)(16)(ii)]; (2) a training and qualification plan in

accordance with the criteria set forth in Appendix B to 10 CFR Part 73 [§ 52.79(a)(36)(ii)]; (3) a description of the radiation protection program required by § 20.1101 [§ 52.79(a)(39)]; (4) a description of the fire protection program required by § 50.48 [§ 52.79(a)(40)]; and (5) a description of the fitness-for-duty program required by 10 CFR Part 26 [§ 52.79(a)(44)]. During the preparation of the final rule, the NRC also noticed that it had not completely implemented the Commission's direction regarding the treatment of operational programs in a COL application because it had failed to add requirements to address program implementation in its revisions to § 52.79(a). Therefore, in the final rule, the NRC has added requirements to address the implementation of all operational programs required to be described in a COL application. This is consistent with the Commission's direction to the staff in SRM-SECY-02-0067 that a combined license applicant was not required to have ITAAC for operational programs if the applicant fully described the operational program and its implementation in the combined license application [emphasis added].

4.8 Question 8: Backfitting - Reproduce backfitting requirements in Part 52

Comment 007-95: Commenters stated that NRC's alternative approach to addressing backfitting was unnecessary to clarify the application of the backfitting rule to Part 52 actions. Commenters stated that the proposed rule included adequate references to § 50.109 and in the various Subparts of Part 52, making replication of this language elsewhere unnecessary. If the NRC deemed the inclusion of such information necessary, several commenters suggested each Subpart in Part 52 include its own standards for backfitting to avoid confusion.

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

Comment 013-4: A commenter expressed support for the NRC's proposed Part 52 protection against backfitting. The commenter supported the NRC's proposed language for 10 CFR 50.109 cross-references to applicable provisions of Part 52, which would provide backfitting protections for the Part 52 licensing process.

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

4.9 Question 9: ESP Updates - Updating environmental and emergency preparedness information

Definition of New and Significant Information

Comments 002-10, 002-12, 002-13, 002-13, 002-14, 002-15, 002-16, 002-17, 002-96: Several commenters were opposed to wording in the text of proposed § 51.50(c)(1) that would require COL applications to include, "any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit environmental impact statement." Commenters stated the COL Application Environmental

Report should not be required to identify all new information regarding previously considered issues. Commenters explained that, consistent with the process and practices used for license renewal, a COL applicant should only provide information about a previously considered environmental issue if it is both new and significant, not simply different from or in addition to previously presented information. Commenters were concerned that the concept of what is “new” was being tied exclusively to what information was in the ESP EIS. They supported a more sharply defined version of what constituted “new” than what existed in proposed §§ 51.50(c)(1) and 52.39(c). Commenters stated the NRC proposed definition would: (1) result in unnecessary and duplicative work for COL applicants and the NRC staff, (2) introduce inefficiencies into the licensing and hearing process, (3) potentially expand any associated hearing, and (4) undermine the value of the ESP. Commenters expressed concern that a party to a COL proceeding could potentially litigate whether the conclusions in the EIS would be changed by any information—any study, any report, any opinion, or any alleged facts—not explicitly discussed in the EIS, as long as that party met the pleading requirements of basis and reasonable specificity, and even if the information was addressed for ESP (but not documented in the EIS).

Commenters requested that at a minimum, no information be deemed “new” if it was considered in preparing the Environmental Report or EIS (as would be evidenced by references in those documents, request for additional information responses, comment letters, and the like), or if it was generally known or publicly available (such as information in reports, studies and treatises) during preparation of the EIS. Commenters advised that the Part 52 final rule and Supplementary Information be amended to reflect a more appropriate definition of “new” information.

NRC Response: The NRC agrees with the commenters. The NRC has removed wording requiring that COL applicants referencing an ESP include “any new and significant information on the site or design to the extent that it differs from, or is in addition to, that discussed in the early site permit environmental impact statement.” Instead, the NRC has modified § 51.50(c)(1) (and related provisions) in the final rule to require that COL applicants referencing an ESP include any significant new information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding. The NRC agrees that a COL applicant should only provide information about a previously resolved environmental issue if it is both new and significant. The final rule states that, in the context of a combined license application that references an early site permit, the NRC defines the term “new” in the phrase “new and significant information” as any information that was not considered in preparing the early site permit environmental report or EIS (as may be evidenced by references in these documents, applicant responses to NRC requests for additional information, comment letters, etc.) or if it was generally known or publicly available during the preparation of the EIS (such as information in reports, studies and treatises). This new information may or may not be significant. For an issue to be significant, it must be material to the issue being considered, i.e., it must have the potential to affect the NRC staff’s evaluation of the issue.

Process for Identifying New and Significant Information

Comments 002-9, 002-11, 002-12, 002-13, 002-14, 002-15, 002-16, 002-95: With respect to ESP environmental information, commenters stated that a COL applicant should have processes for identifying “new and significant” information that causes an adverse change to an

ESP EIS conclusion. The commenters stated that the processes for identifying information and for evaluating whether that information would have an adverse impact on the conclusions in the ESP EIS should be available for the NRC audit at the COL applicant's facilities in a manner comparable to the process used for license renewal. The commenters did not believe that this information should be required or codified in NRC regulations because it was beyond the scope of 10 C.F.R. §§ 52.79(a)(1) and 52.89.

Comment 007-18: Several commenters suggested that the proposed requirement in § 51.50(c)(1) to have COL applications include new and significant information is unnecessary and should be deleted. The commenters do not believe a regulatory requirement is needed for COL applicants when no such requirement has been needed for license renewal.

NRC Response: The NRC disagrees with the majority of the comments. The NRC believes that a combined license (COL) applicant who references an early site permit (ESP) must have a process to identify any significant new information for issues that were resolved in the ESP proceeding. The NRC also believes that its review of environmental information provided in a COL application that references an ESP will be significantly enhanced by having a description of the applicant's process used to identify new and significant information regarding the NRC's conclusions in the early site permit environmental impact statement.

This belief is based on the quality and level of detail of information that was used in the earlier analysis. For license renewal, the NRC performed the analysis of environmental effects during the renewal period for each of the operating plants and for those plants with a construction permit for a specific design; the NRC also had the benefit of the operating experience of over 100 units for an extended period of time to support its analyses. For new plants where the environmental impacts of construction and operation are resolved in the ESP proceeding, the conclusions are based on analytical methods and assumptions regarding the design, construction and operation of the facility. However, some of the information about the design, construction practices, and proposed operations is not well known at the time of the ESP application. For these reasons and based on its experience in the review of environmental information in license renewal applications, the NRC believes that having a description of the process for identifying new and significant information in COL applications will enhance the effectiveness and efficiency of the licensing process by providing greater focus to the NRC's subsequent audit of the COL applicant's process for identifying new and significant information. In evaluating whether there is new and significant information at the COL stage, the NRC staff will independently be responsible for the reliability of all information used. Consequently, if the NRC is to rely upon information presented by the proponent of the action, then it must have confidence in the measures taken by the applicant to identify new and significant information that may have arisen during the intervening period between the ESP proceeding and the COL application.

Updating ESPs

Comments 007-96, 011-19: Several commenters believed an ESP holder should not be required to update the information in the ESP application. These commenters stated that the proposal to require updating would add an unnecessary additional level of review (and possibly hearings) with little or no additional benefit (*i.e.*, the COL applicant would still be under the obligation to update the information provided by the ESP holder). Commenters contended that

an updating requirement would only serve to erode the finality and certainty provided by the ESP, thereby defeating one of the purposes of an ESP. Commenters also believed that an updated requirement would run counter to NRC regulations. Commenters stated that while the ESP is in effect, the NRC cannot change or impose new requirements, including emergency planning requirements, unless it determines that a modification is necessary either to bring the permit or the site into compliance with the NRC's regulations and orders applicable and in effect at the time the permit was issued, or to assure adequate protection of the public health and safety or the common defense and security. Commenters argued that the proposed 18-month updating requirement may not be feasible. A commenter gave the following example, "under the NRC's current schedule for the existing ESP applications for North Anna and Grand Gulf, the ESPs will not be issued until 2007, shortly before the planned COL applications for those sites. This would result in insufficient time for the updating envisioned by the NRC, and it would be unfair to those applicants to require them to delay their COL applications to accommodate the updating process. Additionally, the proposed updating process would be inconsistent with 10 CFR 52.27(c), which permits a COL application to reference an ESP application."

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

Several commenters expressed the belief that a COL applicant should be able to make changes or updates to ESP emergency planning information without NRC approval in accordance with the criteria in 10 CFR 50.54(q) just as the remaining safety information can be revised under 50.59 once it has been reviewed and approved (see excerpt 007-46 in summary Section 5.3.2 for further discussion of this topic). The commenters also stated that this revised information should not be considered as an "amendment" submitted under 50.90 for review and approval, but rather should be considered to be information equivalent to that provided under § 50.71(e) for information.

NRC Response: The NRC agrees with the commenter that ESP holders should not be required to update the information in the ESP application. NRC also agrees with the commenter that the ESP holder should have the option of requesting an ESP amendment in order to resolve issues not previously addressed, and has added rule language to Sections 50.90 through 50.92 to include ESP holders. The NRC agrees that a COL applicant can use the authority under §52.27(c) to reference a site for which an ESP application had been docketed but not approved; if an amendment to the ESP is granted, it would then be part of the pending ESP application. The response to the comment concerning changes to ESP emergency planning information using §50.54(p) is discussed in Section 5.3.2 of this report.

4.10 Question 10: Living Probabilistic Risk Assessment (PRA) - Update of PRA and schedule for update

Comment 007-97: Several commenters noted the NRC had stated that PRA scope and methods should be addressed in guidance, not in regulations (SRM on SECY-05-0203). Commenters supported the notion that PRA update frequency be addressed in guidance rather

than regulations. Commenters indicated a frequency of once every two operating cycles would be reasonable and consistent with existing requirements in 10 CFR 50.69(e).

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

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

NRC Response: The NRC staff agrees with the basic intent of the industry comment regarding NRC Question 10, "New Requirements for Periodic Updates to the PRA," which is that the rule does not need to explicitly require combined license holders to submit to the NRC all changes to the PRA computer models (including fault trees and event trees, etc.) on a periodic basis. In DG-1145, the staff guidance does state that the COL applicant should describe their PRA maintenance and update program in Chapter 19 of their FSAR, but does not require the resubmittal of the PRA or submittal of changes to the PRA (i.e., submitting revised fault trees and event trees, etc.). It is expected that these PRA models will be maintained by the licensee to reasonably reflect the as-built, as-operated plant and will be available for NRC staff audit. In addition, the DG-1145 guidance also states that the licensee should periodically update FSAR Chapter 19 to describe plant and operational changes that have a significant impact on the PRA results and insights (as well as updating the description of the affected PRA results and insights).

Based on the above discussion and the regulatory guidance provided in DG-1145, the staff agrees with the industry that the proposed new requirement, identified in NRC Question 10, is not necessary.

4.11 Question 11: AP1000 - NEI-proposed changes for DCRs

Comment 007: Several commenters recommended the NRC incorporate the NEI recommendations on the AP 1000 rule, cited specific NEI recommendations (71 FR 12834-12836), and made additional suggestions and clarifications.

NRC Response: The NRC has reconsidered the comments from NEI on the AP1000 design certification rule (DCR) that were generic to all of the DCRs in appendices A - D of Part 52. The NRC's resolution of the generic DCR comments are set forth in the responses to question 11 in

Section IV of the Federal Register Notice. The additional comments on question 11 that were submitted by NEI are discussed below.

Comment 007-98: Regarding NEI recommendations (a) and (b), several commenters suggested it would be sufficient if the Statements of Considerations for the final rule provided the requested clarification, rather than the rule itself.

NRC Response: The NRC agrees with this comment and believes that the section-by-section analysis for the AP1000 DCR (71 FR at 4475) provides the necessary guidance on bracketed information in the generic technical specifications and the investment protection short-term availability controls.

Comment 007-99: Regarding NEI recommendation (f), several commenters supported the use of the term “include” rather than “physically include” for requirements in Section IV of the design certification rules concerning content of COLAs.

Commenters requested clarification on the permissible method of incorporating the generic DCD into the plant-specific DCD portion of the COL application’s final safety analysis report (FSAR), because the current NRC position has apparently “led to considerable confusion” among COL preparers. Commenters noted that in the Statements of Consideration accompanying the AP1000 final rule, NEI recommended a change to the Definitions (Section III.B of that rule, 71 FR 4466). Commenters stated the NRC staff disagreed with this recommendation, saying that “the generic DCD should also be part of the FSAR, not just incorporated by reference, in order to facilitate the NRC staff’s review of any departures or exemptions.” Commenters believed that this NRC position was in conflict with the current § 52.79(b), which states that the COL application’s FSAR “may incorporate by reference the final safety analysis report for a certified standard design,” and with § 50.32, which provides for incorporation by reference to eliminate repetitive information. Commenters argued that although the wording had been altered, the ability to incorporate by reference was preserved in proposed §§ 52.79 (b) and (c), respectively. Commenters claimed this interpretation of incorporation was validated by NRC staff during the DG-1145 workshops. The commenters stated support for this interpretation and requested the NRC explicitly describe that either approach is acceptable.

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

Comment 007-100: While discussing NEI recommendation (j), several commenters mentioned Section VIII.B.6.a of the design certification rules, which states that an applicant who references the design certification rule must obtain NRC approval for departures from Tier 2* information in the generic DCD. Commenters believed that this section states the departure is not considered to be a resolved issue under Section VI of the design certification rules. Commenters indicated this was inconsistent with Section VI.B.5 of the design certification rules, which states that license amendments are considered to be resolved. Commenters expressed support for the revision of Section VIII.B.6. of the design certification rules to make it consistent with Section VIII.B.5 of the design certification rules. Commenters stated that departures from Tier 2* information that are reviewed and approved by the NRC in the combined license proceeding should have finality for the plant in question.

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

Comment 007-101: With respect to NEI recommendation (k), several commenters expressed concern that Section VIII.C.3 of the design certification rules “inappropriately” allowed the NRC to make changes to operational requirements in the DCD without satisfying the backfit requirements in § 50.109. Commenters stated that the operational requirements in the design certification proceeding should be afforded the protection of the backfit rule. Commenters supported a revision to Section VIII.C.3 of the design certification rules to include a reference to § 50.109 for these changes.

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

Comment 007-102: In the discussion of NEI recommendations (l) and (m), several commenters mentioned Section VIII.C.4 of the design certification rules, which states a COL applicant must request an exemption from the NRC if the applicant wants to depart from the generic technical specifications or other operational requirements. Commenters described this requirement as “unduly burdensome.” Commenters noted that the operational requirements do not have finality under Section VI.C of the design certification rules, and that no basis existed for applying such a change control process to a COL applicant seeking to change operational requirements. Commenters cited Section VIII.B.5 of the design certification rules, which states a COL applicant may depart from final design-related provisions in the design certification rule using a “50.59-like” process, and argued that imposing an exemption process with respect to operational provisions was not required. Commenters recommended Section VII.C.4 be

amended to state that a departure from an operational requirement does not require an exemption.

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

Comment 007-103: Several commenters mentioned information from NEI's September 30, 2003, response to the 2003 Part 52 Notice of Proposed Rulemaking. Commenters expressed support for the need to add a basic definition of "departure" to the DCRs to be consistent with adding the definition of "departure from a method of evaluation," and stated that both should be based on Regulatory Guide 1.187. Commenters stated, "The basic definition of 'change or departure' should precede the definition of departure from a method of evaluation." Commenters recommend adding the new definition as paragraph II.G and renaming the final two paragraphs as II.H and II.I.

NRC Response: The NRC does not agree with the recommendation to add a definition of "departure" to Section II of the DCRs. The NRC has provided an explanation of the term "departure" as used in the DCRs in Section V.C.4 of the Federal Register Notice.

4.12 Question 12: ITAAC Schedule - ITAAC required prior to fuel loading

Comment 007-105: Several commenters believed it was unnecessary to include a requirement for either the COL applicant or the COL holder to submit a detailed schedule for ITAAC completion because a COL applicant could provide only a progressively less accurate estimated completion schedule. Commenters stated that the COL holder would have schedules at the site, and those schedules would be available for NRC review. Commenters believed that COL holders would interact and coordinate with the NRC to ensure that NRC had sufficient information to schedule its inspection activities for ITAAC, making a regulatory requirement for submission of a schedule unnecessary. In addition, the commenters noted that a COL applicant/holder would likely consider detailed schedule information proprietary information, which would make its submission, in this case, inappropriate.

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

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

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

Commenters did not support addition of a requirement on completion of ITAAC in a set time period prior to fuel load and the NRC has not included a provision requiring the completion of all ITAAC by a certain time prior to the licensee's scheduled fuel load date. Instead, the NRC has decided to modify the concept slightly by requiring the licensee to submit, with respect to ITAAC which have not yet been completed 180 days before the scheduled date for initial loading of fuel, additional information addressing whether those inspections, tests and analyses will be successfully completed and the acceptance criteria met before initial operation. In the case where the licensee has not completed all ITAAC by 180 days prior to its scheduled fuel load date, the NRC expects the information that the licensee submits related to uncompleted

ITAAC to be sufficiently detailed such that the NRC can determine what activities it will need to undertake to determine if the acceptance criteria for each of the uncompleted ITAAC have been met, once the licensee notifies the NRC that those ITAAC have been successfully completed and their acceptance criteria met. In addition, the NRC is adopting the requirements in paragraphs (c)(1) and (c)(2) to ensure that interested persons will be able to meet the Atomic Energy Act, Section 189.a(1), threshold for requesting a hearing with respect to both completed and as-yet uncompleted ITAAC. The NRC therefore expects that the information submitted by licensees in the § 52.99(c)(2) notification will be sufficiently complete and detailed such that any licensee response to a contention on both completed and uncompleted ITAAC would ordinarily be answered solely by reference to information contained in the notification. Furthermore, the NRC expects that any contentions submitted by prospective intervenors regarding uncompleted ITAAC would focus on the inadequacies of the procedures and analytical methods described by the licensee for completing those ITAAC in the context of the reasonable assurance finding under § 52.103(b)(2). Therefore, the level of detail provided by the licensee should be sufficient to allow a prospective intervenor to form such judgments by reference to that information. The NRC plans to prepare regulatory guidance providing further explanation of what constitutes “sufficient information” to demonstrate that the inspections, tests, or analyses for uncompleted ITAAC will be successfully completed and the acceptance criteria for the uncompleted ITAAC will be met.

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

4.13 Question 13: ML Hearing - Provide opportunity for hearing by rule

Comments 007-106, 005-27(a), 005-22: Several commenters stated there was no need to require mandatory hearings for manufacturing licenses, or that the need for such hearings was unclear. Commenters expressed the belief that such hearings were not an appropriate method for reviewing and resolving technical issues. Commenters advised that the decision to request a hearing be left to either the NRC staff or stakeholders.

NRC Response: As stated in the statement of considerations for the March 13, 2006, proposed rule, the NRC acknowledges that hearings on initial issuances of manufacturing licenses are not required by the AEA (71 FR at 12814). The NRC also agrees with the general premise of the commenters that adjudicatory hearings may not be the best approach for resolving technical design issues - especially in uncontested proceedings. Indeed, the NRC removed the opportunity for adjudicatory-style hearings for design certifications as part of the 2004 changes

to 10 CFR Part 2 (January 14, 2004; 69 FR 2182). The primary responsibility for determining the safety of an application is with the NRC staff, and not the presiding officer. This is true regardless of whether the proceeding is contested or uncontested. Public confidence would not seem to be enhanced in any significant manner by the holding of a hearing where there is no request that the NRC hold a hearing. Accordingly, the NRC has decided not to adopt in the final Part 52 rule a requirement for a "mandatory" hearing in connection with issuance of manufacturing licenses.

4.14 Question 14: DCR Changes - Changes to design certification rules

Comments 006-2, 006-3, 006-4, 006-5, 007-9, 007-107, 009-3, and 016-2: Several commenters urged that current § 52.63 should be revised to allow the design certification applicant to obtain amendments to the design certification rule. The applicant should be able to petition the Commission for an amendment to incorporate "beneficial" changes to the design certification. Current NRC regulations appear to prevent any amendment to a design once the design has been certified by rule. Additional design work and other circumstances may result in a need for the applicant to make an amendment. Proposed changes should be permitted where they maintain both protection of the public health and safety and common defense and security. Such a process would result in worthwhile benefits in terms of improvements in safety, efficiency, and reliability relating to the design, construction, and operation of the plant. Amendments to the design certification rule to make beneficial changes should be permitted until the first COL referencing the design has been issued. If changes are needed after one or more nuclear power plants utilizing an approved standardized design are licensed and operating, then the amendments should only apply to plants that are not yet in operation.

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

4.15 Question 15: Part 21 - Impose Part 21 reporting requirements on applicants during ESP and DC process

Comments 007-3 and 007-108: Several commenters were opposed to the proposed changes to Part 21. Commenters stated Part 21 had been in existence for almost 30 years, during which time it was never applied to applicants. They complained that they were not aware, and the NRC had not made them aware, of problems that would warrant a change. The commenters noted that applicants take measures to ensure that they were made aware of any errors and deficiencies identified by contractors and suppliers for work performed on commercial nuclear projects, because applicants eventually become holders, and licensees and want equipment to operate correctly. Several commenters were also concerned that the proposal was contrary to the Energy Reorganization Act (ERA), which was the basis for Part 21. They believed it would be inappropriate and contrary to the ERA to apply Part 21 to applicants. They stated Part 21 was established to implement Section 206 of the ERA, which

applies to “licensees” and vendors, suppliers, and contractors of licensees, not to “applicants.” The commenters cited 10 CFR 21.2, stating that the existing regulations of Part 21 apply only to entities licensed to possess, use, or transfer radioactive material within the United States, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or fuel storage facility. The commenters believed applicants did not fall within the scope of Section 206 of the ERA, and it was inconsistent with the Act to expand the scope of § 21.2 to include applicants.

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

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

NRC Response: The Commission proposed Part 21 reporting requirements on applicants for early site permits, design certifications, and standard design approvals in the proposed rule. A detailed discussion on the Commission’s rationale for imposing these requirements in the final rule is provided in Section V.J of the Supplementary Information in the Federal Register notice.

5 Discussion of Substantive Changes and Response to Significant Comments

No comments received.

5.1 Introduction

No comments received.

5.2 Testing Requirements for Advanced Reactors

Comment 007-21: Several commenters noted that proposed 10 CFR§ 52.79(a)(24) and 50.43(e) would impose new testing requirements for COL applicants planning to build advanced designs that have not been certified. The commenters stated that the proposal conflicts with the Commission’s intent expressed in the original 1989 Statement of Considerations for Part 52 and may also present an undue burden and obstacle to commercialization of advanced designs.

The commenters explained that, in essence, proposed §§ 52.79(a)(24) and 50.43(e) would require that the same testing required of a design certification applicant be performed by a COL applicant that seeks a license for a non-evolutionary custom plant. The commenters noted that the proposed rule would require either (A) analysis, testing or experience, or (B) full-scale

prototype testing. The commenters also noted the Commission's statement that, for design certification of advanced reactors, it favors the use of a full-scale prototype in lieu of the other alternatives (51 FR 24643). The commenters believe it is unnecessary to apply these requirements to COL applicants, and that the potential requirement for a full-scale prototype testing is particularly inappropriate.

The commenters asserted that exercising the proposed COL requirement for prototype testing would create a logical disconnect. The commenters stated that absent a license, a prototype commercial nuclear plant cannot be built in the United States. The commenters noted that on the other hand, under the proposed rule, absent construction of a prototype, the design could not be licensed. The commenters stated that this "Catch-22" situation would effectively close an important path for bringing to market nuclear plant designs with innovative safety features. The commenters recommended that for these reasons, it would be inappropriate to establish or impose proposed § 50.43(e) (prototype testing) on COL applicant. In the alternative, the commenters suggested that the Statement of Considerations for the final rule should clearly state that the NRC does not prefer the use of prototypes over analysis, testing, or experience for licensing of reactors advanced reactors, and that the NRC may issue a COL for a prototype plant.

NRC Response: The NRC does not agree that the testing requirements for COL applicants conflict with the Commission's intent for Part 52 or that the requirements are unnecessary. When the Commission reformed the licensing process for new nuclear plants with the issuance of Part 52, it required applicants to demonstrate that the new safety features will perform as predicted in the final safety analysis report. Although the focus of the NRC at that time was on applications for design certification, the Commission intended that testing to qualify new design features (proof-of-performance testing) would be required for all advanced reactors, including custom designs (see Question 6 at 51 FR 24646; July 8, 1986). Furthermore, it would make no sense for the NRC to require qualification testing for design certification applicants (so-called paper designs) and not require testing for applications to build and operate an advanced nuclear power plant. Therefore, the NRC has implemented its intent in adopting Part 52 to resolve issues early and its policy on advanced reactors that it is necessary to demonstrate the performance of new or innovative safety features through design qualification testing for all advanced nuclear reactor designs or plants (including nuclear reactors manufactured under a manufacturing license).

The NRC also disagrees with the claim that the requirement for prototype testing would create a logical disconnect. The final rule provides an option in § 50.43(e)(2) for licensing a prototype plant, if the plant will be used to meet the testing requirements in § 50.43(e)(1). The new § 50.43(e) states that, if a prototype plant is used to comply with the qualification testing requirements, the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to compensate for any uncertainties associated with the performance of the new or innovative safety features in the prototype plant. Therefore, an applicant could request a COL for a prototype plant to meet the testing requirements.

Commenters stated that it would be inappropriate to establish or impose prototype testing on combined license applicants. Although the Commission stated that it favors the use of prototypical demonstration facilities and that prototype testing is likely to be required for certification of advanced non-light-water designs (see Advanced Reactor Policy Statement at 51 FR 24646; July 8, 1986, and 10 CFR Part 52 at 54 FR 15372; April 18, 1989), this rule does

not require the use of a prototype plant for qualification testing. Rather, this rule provides that if a prototype plant is used to qualify an advanced reactor design, then additional conditions may be required for the licensed prototype plant to compensate for any uncertainties with the unproven safety features.

The commenters stated that the fact that current § 52.79 does not reference the prototype testing requirements in § 52.47(b)(2)(i) was no mere oversight - it was intentional. The commenters noted that the Statement of Considerations for both the original proposed Part 52 (53 FR 32060, August 23, 1988) and the final Part 52 (54 FR 15372, April 18, 1989) indicate that design certification and licenses are to be treated differently with respect to prototype testing. The commenters cited several examples that the Commission wrote in those two rules. [See 53 FR 32063-64 and 54 FR 15374-75, 15383]

In addition, the commenters noted that the original 1986 Commission Policy Statement on Regulation of Advanced Nuclear Power Plants (51 FR 24643, July 8, 1986) indicated that the intent of the revised licensing process was to minimize complexity and uncertainty in the licensing process. The commenters stated that the addition of a prototype plant testing requirement minimizes neither the complexity nor the uncertainty, but rather adds to the uncertainty by inserting a significant additional step (currently representing an unknown quantity) prior to the licensing of a plant of a new design.

NRC Response: The commenters have misinterpreted the Commission's requirements and policy on prototype plants. The Commission's policy on the licensing processes in Part 52 is to provide alternatives to the licensing process in Part 50. As stated above, the requirement in § 50.43 provides an option for licensing a prototype plant to perform testing of safety features.

The commenters noted that the Commission has stated that prototype testing will likely be required for design certification of advanced reactors. However, the commenters stated that there are significant differences between certified and custom designs. The commenters noted that a certified design is effective for 15 years, may be incorporated by reference by any license applicant without further review and approval by the NRC, and is subject to broad protection against backfits under the change control process in 10 CFR 52.63.

The commenters noted that in contrast, the arguments for prototype testing for certification of advanced reactors do not apply to licensing of advanced reactors. The commenters asserted that unlike a design certification, licensing represents approval of only a single facility. The commenters stated that licensing of subsequent facilities, even if identical in design, is still subject to NRC review and approval including possible design changes to account for any unfavorable results of startup and power ascension testing and operating experience from previously licensed facilities. The commenters further stated that, unlike a design certification, the NRC has fairly broad authority under 10 CFR 50.109, "Backfitting," to impose backfits on a licensed facility to account for any unfavorable results of startup and power ascension testing and operating experience. The commenters stated that finally, in lieu of prototype testing, the NRC has authority to impose special license conditions that might not be necessary or appropriate if applied to all plants with a standard design (e.g., a license condition can require special design, procedural, or testing provisions to provide adequate protection of safety until the design is demonstrated to be safe through testing or operation). The commenters recommended that because of these arguments, there is no compelling reason for a full-scale prototype test facility prior to licensing of an advanced reactor.

NRC Response: Once again, commenters have misinterpreted the Commission's requirements and policy on prototype plants. As stated above, the final rule does not require the use of a prototype plant for qualification testing. Rather, this rule provides that if a prototype plant is used to qualify an advanced reactor design, then additional conditions may be required for the licensed prototype plant to compensate for any uncertainties with the unproven safety features.

The commenters stated that it is simply unnecessary to impose on COL applicants the requirements of § 50.43(e) to demonstrate safety features via analysis, testing, and/or experience. The commenters stated that this is because the COL applicant is already subject to 10 CFR 50.34(b)(4) requirements to provide sufficient information of this type to support the required NRC safety determination on the design. The commenters also stated that in addition, at COL issuance, the NRC has authority to establish license conditions, including conditions on successful demonstration of unique design features.

The commenters noted that NRC guidance and past precedent indicate that a full-scale prototype testing facility need not precede licensing of a new type of reactor. The commenters noted as an example that NRC Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - LWR Edition," which provides the standard format and content for safety analysis reports, explicitly states that special, unique, or first of a kind design features may be verified through startup test. [See NRC Regulatory Guide 1.70, Section 14.1.2.]

Similarly, the commenters noted that NUREG-0800, "Standard Review Plan" Section 14.2, Paragraph III.8, recognizes that the initial test program in FSARs may include provisions for "testing for special, unique, or first-of-a-kind design features." The commenters stated that therefore, NRC guidance clearly allows for testing of unique and first-of-a-kind design features through the startup and power ascension test program, and does not require prototype testing prior to issuance of a license for a plant involving such features. The commenters concluded that through its existing requirements and regulatory authority, the NRC may assure that applicants provide adequate information to support required COL reviews and safety determinations, as well as satisfactory demonstration of innovative design features during startup and power ascension testing.

NRC Response: As stated above, commenters continue to misinterpret the Commission's requirements for demonstration of new safety features. The requirements in § 50.43 for demonstration testing are unrelated to the requirements for safety analyses in § 50.34(b)(4). However, the NRC agrees that the COL for a prototype plant will contain conditions on the successful demonstration of new design features. Also, regarding the references to NRC Regulatory Guide 1.70 and NUREG-0800, Section 14.2, commenters have confused verification testing for approved design features with the testing that is necessary to demonstrate new design features.

5.3 Changes to 10 CFR Part 52 (Subparts A - H)

Referencing ESPs and Design Certifications in COL Applications

Comment 005-1: A commenter suggested that the NRC's discussion of the regulatory changes (page 12786 of the Federal Register notice) focuses narrowly on the idealized process

envisioned when Part 52 was originally developed: a combined license (COL) application that references previously completed early site permit (ESP) and design certification (DC) proceedings. The commenter believes that this approach ignores the fact that none of the COL applications (COLAs) that have been announced for submission to the NRC in the 2007-2008 time frame will reference both an already-certified design and an ESP. The commenter pointed out that those COLAs that will reference a DC do not involve ESPs, while those that will reference completed ESPs will not reference a design for which certification is complete. The commenter suggested that lack of consideration of the actual types of cases with which the NRC will be presented results in regulatory requirements that are, in some cases, not well-suited for use by potential COL applicants whose approach varies from the one stated above. The commenter encouraged the NRC to focus on developing rules that are equitable and clearly applicable for all potential COL applicants.

NRC Response: The Commission disagrees with both the commenter's observation that the SOC's discussion of the regulatory changes focuses on the "idealized process" of a combined license referencing both an early site permit and a standard design certification, as well as the commenter's suggestion that the NRC failed to consider the actual types of cases for which the NRC will be presented. A fair reading of the both the SOC and the provisions of the proposed rule demonstrates that no particular course of action is favored or encouraged; Part 52 is structured to provide the combined license applicant many different alternatives. The Commission also finds it presumptuous of this commenter to suggest that it knows what "actual types" of applications will be submitted to the NRC in the future. While current prospective applicants may decide to utilize a particular approach for pursuing a combined license application because of their own circumstances and business imperatives, the Commission cannot bias its regulations in such a manner unless the Commission believes that there are sound regulatory reasons for doing so. The commenter presented no information that constitutes such regulatory basis.

Comment 007-8: Several commenters noted that § 52.55(c) allows a construction permit or COL applicant, at its own risk, to "reference in its application a design for which a design certification application has been docketed but not granted." Several NRC licensees and/or consortia are considering filing COL applications that reference a DC application. Because Part 52 currently does not specify the procedures to be followed in such a situation, further direction from the NRC is now needed as to how § 52.55(c) should be implemented. Specifically, the commenters recommended that the NRC revise § 52.55(c) to provide clarification and direction on handling COL applications that reference DC applications. Such guidance is needed to enhance the efficiency of both the NRC staff's review and the conduct of NRC hearings on COL applications that reference a DC application. Industry's goal in this regard is to preclude the NRC staff and the NRC Atomic Safety and Licensing Board from conducting duplicative review of DC application issues in the COL proceeding pending issuance of the final DC. Such redundant licensing reviews and/or redundant litigation of DC standard design issues in connection with a COL application will almost certainly delay and further encumber the Part 52 licensing process, with no attendant increase in the protection of public health and safety or the environment. Such redundant reviews would pose the potential for inconsistent results in the multiple proceedings, and possibly the loss of standardization.

NRC Response: The Commission does not agree with the commenters that rulemaking changes should be adopted to specify in detail the review procedures and hearing matters to be

utilized when a combined license application references either an proposed (rather than final) standard design certification rule, or a early site permit application, or both. The Commission believes that codifying a specific approach for conducting such a proceeding, which is not likely to be used extensively by applicants, for which there is no Commission experience, and for which the Commission did not request stakeholder input on, would not be prudent. The Commission believes that existing law and the inherent flexibility afforded by Part 52 and Part 2, may the basis for issuance of generic guidance or case-specific Commission action addressing this matter. For these reasons, the Commission declines to adopt the commenters' proposal, and no change to any part of the final rule has been made as the result of the comments.

Comments 007-8, 013-8: Several commenters noted that 10 CFR 52.27(c) allows a construction permit or COL applicant, at its own risk, to “reference in its application a site for which an early site permit application has been docketed but not granted.” The commenters continued to note that § 52.55(c) allows a construction permit or COL applicant, at its own risk, to “reference in its application a design for which a design certification application has been docketed but not granted.” The commenters stated that beyond this permissive language, the regulations provide no further detail and that the current proposed amendments to 10 CFR Part 52 do not propose changes to §§ 52.27(c) or 52.55(c). [See 71 FR 12892, 12897.]

The commenters stated that, consistent with existing §§ 52.27(c) and 52.55(c), several NRC licensees and/or consortia are considering filing COL applications that reference an ESP application or a DC application. The commenters stated that because 10 CFR Part 52 currently does not specify the procedures to be followed in such a situation, further direction from the NRC is now needed as to how §§ 52.27(c) and 52.55(c) should be implemented. This topic (under the heading of the need for “licensing flexibility” in the new 10 CFR Part 52), was specifically mentioned in NEI’s December 14, 2005, letter to NRC Chairman Diaz responding to questions and comments raised in the November 21, 2005, NRC-industry meeting. The commenters went on to state that one advantage of addressing this issue in the ongoing Part 52 rulemaking is that the NRC could thereby provide a clear, definitive, and generic regulatory solution to this question. Further, the commenters believe that the promulgation of a more detailed process in 10 CFR§ 52.27(c) and 52.55(c) would be consistent with the Commission’s recent directive to the NRC staff to include in the Part 52 rulemaking “proposed strategies for staff review of expected applications and support for COL hearings before the Atomic Safety and Licensing Board Panel.” [See Jan. 30, 2006 Staff Requirements Memorandum re SECY-05-0203 from the Commission, p. 3.]

Specifically, the commenters recommended that the NRC revise 10 CFR§ 52.27(c) and 52.55(c) to provide clarification and direction on handling COL applications that reference ESP or DC applications. The commenters stated that such guidance is needed to enhance the efficiency of both the NRC staff’s review and the conduct of NRC hearings on COL applications that reference an ESP or DC application. The commenters noted that Industry’s goal in this regard is to preclude the NRC staff and the NRC Atomic Safety and Licensing Board (Licensing Board) from conducting duplicative reviews of DC and ESP application issues in the COL proceeding pending issuance of the final DC and ESP. The commenters stated that such redundant licensing reviews and/or redundant litigation of ESP siting issues and DC standard design issues in connection with a COL application will almost certainly delay and further encumber the Part 52 licensing process, with no attendant increase in the protection of public health and safety or the environment. The commenters stated that redundant licensing reviews

for new plants are also inconsistent with the Commission's stated goal, in the current rulemaking, to "more effectively and efficiently implement the licensing and approval processes for future nuclear power plants under Part 52." [See 71 FR 12783.] The commenters continued to state that such redundant reviews would pose the potential for inconsistent results in the multiple proceedings, and possibly the loss of standardization.

In particular, the commenters proposed that the text of §§ 52.27(c) and 52.55(c), and/or the discussion on the Statements of Consideration accompanying the NRC final rule, make the following points: (1) the hearing for a COL application may proceed pending issuance of the ESP or DC referenced in the COL application, provided that a docketed ESP or DC application precedes the docketed acceptance date of the COL application; (2) the issues that will be addressed in the referenced ESP proceeding or the DC proceeding/rulemaking may not be addressed in the COL application hearing, and may not form the basis for admissible contentions in the COL proceeding, except as may be combined in a single license proceeding under § 52.8, and that the Licensing Board presiding in the COL hearing would defer consideration of matters to be resolved in the ESP or DC proceeding, including any contentions adjudicated in those proceedings; however, litigation on other COL issues would proceed; (3) the COL application hearing should be based upon the information contained in the DC application and/or ESP application, as amended at the time of COL application hearing commences, and if the DC application or ESP application were to change after the conclusion of the COL application hearing, additional hearings may be necessary if those changes impact the issues considered in the COL proceeding; (4) that upon issuance of the ESP or DC, the COL applicant would amend the COL application to reference and conform to the final ESP or DC; (5) the commencement of a COL hearing for a COL referencing a pending ESP or DC application would be at the risk of the COL applicant, consistent with existing §§ 52.27(c) and 52.55(c).

The commenters stated that underlying this proposed regulatory approach is the assumption that a COL application referencing an ESP or DC application should be treated similarly to a COL application that references a final ESP or DC. [See 10 CFR 52.73] The commenters stated that in terms of the licensing review, they propose that the NRC staff and the Advisory Committee on Reactor Safeguards (ACRS) would review siting issues in the context of the ESP proceeding and standard design issues in the context of the DC proceeding. The commenters stated that in the COL proceeding, the staff and the ACRS would subsequently rely upon these previous reviews and treat siting matters and standard design matters as final, thereby avoiding duplicative reviews of siting and/or design issues in the COL proceeding.

The commenters suggested that, regarding the interface between the COL proceeding and the ESP or DC application, the NRC staff and ACRS would assume that the information in the ESP or DC application is final. If the referenced ESP or DC application is later amended, the staff and ACRS would account for that amendment in their review of the COL application, and the applicant would amend the COL application as needed.

In addition to revising the text of the affected regulations in either Part 2 or Part 52, the commenters asked that the NRC staff include explanatory language addressing these concepts in the Statements of Consideration accompanying issuance of the final rule amending 10 CFR Part 52, to provide maximum clarity on these points.

NRC Response: The Commission does not agree with the commenters that rulemaking changes should be adopted to specify in detail the review procedures and hearing matters to be utilized when a combined license application references either an proposed (rather than final) standard design certification rule, or early site permit, or both. The Commission believes that codifying a specific approach for conducting such a proceeding, which is not likely to be used extensively by applicants, for which there is no Commission experience, and for which the Commission did not request stakeholder input on, would not be prudent. The Commission believes that existing law and the inherent flexibility afforded by Part 52 and Part 2, may be the basis for issuance of generic guidance or case-specific Commission action addressing this matter. For these reasons, the Commission declines to adopt the commenters' proposal, and no change to any part of the final rule has been made as the result of the comments.

Retroactivity of Proposed New Requirements on Existing and Pending ESP and Design Certifications at the Time of Adoption of the Final Rule

Comments 006-7, 007-7, 012-10: Several commenters noted that the Proposed Rule contains more than thirty new requirements on applicants for ESPs and design certifications. However, the commenters noted that the Proposed Rule is silent on whether the proposed new requirements would be imposed on applications for ESPs pending and/or on ESPs which already have been issued at the time of adoption of a final rule. The commenters noted that the Proposed Rule is also silent on whether the proposed new requirements would be imposed on designs which already have been certified, on applicants for those certified designs, and/or on applicants for designs which have not yet been certified at the time of issuance of a final rule.

The commenters also noted that the proposed rule is silent on whether, in the COL licensing process, the new requirements could be raised and imposed on a COL license applicant who references an ESP or a certified design. The commenters stated that this would reopen, via the "back door," the ESP or the certified design. The commenters clarified that the Proposed Rule leaves open the question of whether an ESP or standardized design that is referenced in the COL licensing process (including any licensing hearing) will be subject to reopening because of the adoption by the Commission of the new requirements in the Proposed Rule.

The commenters went on to state that possible retroactive application of the proposed new requirements on existing ESPs or certified designs, or on pending applications for ESPs or design certifications at the time of adoption of the final rule, "introduces new, substantial uncertainty into the Part 52 process and is very troubling." The commenters believe that to apply the new regulations retroactively "would frustrate the idea of finality, which is a cornerstone of Part 52." The commenters noted that for the Commission to have certified a design, the Commission must have been satisfied that relevant Commission regulations were met. The commenters stated that it must be inherent in the certification of a design that no alternative or additional features are required for the design and that all safety issues associated with the design have been satisfied. The commenters continued that similarly, for the Commission to have issued an ESP, they must have been satisfied that applicable Commission regulations were met.

The commenters noted that a representative of their group raised the question of no retroactivity of the Proposed Rule in the NRC Stakeholders Meeting to Discuss Proposed Rule

Change 10 CFR Part 52 (Transcript, p. 15 1). The commenters noted that the NRC representative responded affirmatively to this assumption (Transcript, pp. 151 - 152):

One of the commenters also stated that, as a general matter, no change should be made retroactive if it would affect or delay a current proceeding. The commenter noted that the proposed changes include provisions that might affect the form or contents of ESP applications, as well as the staff's safety analysis report and EIS. The commenter noted as an example that proposed § 52.17(a)(1)(x) would add a new requirement to evaluate the potential hazards of construction activities on existing units, which is a requirement that is currently inapplicable to an ESP application. The commenter also noted that other new requirements would be imposed by proposed §§ 52.17(a)(1)(xii) - (xiii), 52.17(c), and 52.24(a)(4). The commenter stated that if it were necessary to revise pending applications and NRC staff review documents as a result of such changes, the current proceedings could be delayed considerably. The commenter asserted that this would penalize the companies that have undertaken to demonstrate the new licensing process.

Thus, the commenters support the NEI position that any final rule adopted by the Commission should include a "grandfather" clause to exempt ESPs and certified designs that are in existence, and applications for ESPs and certified designs that are pending, on the effective date of any new requirements. The commenters stated that any new requirements promulgated by the Commission should not apply to ESPs that have been issued or standard designs that have been certified prior to promulgation of the new requirements; and any new requirements should only apply to ESP applications and certified design applications filed after the effective date of the new regulations.

NRC Response: The Commission does not agree with commenters suggesting that a grandfather clause is needed for existing design certifications. The four standard design certifications already issued are not be subject to new technical requirements as the result of the final Part 52 rule because any technical changes in Part 50 or elsewhere in Title 10 of the CFR." Moreover, changes in Part 52 which apply to the content of applications or the process and criteria for consideration of design certification applications are not applicable to already-issued design certification rules. Finally, an all-inclusive grandfathering clause would exclude the existing design certification rules from the several burden reduction and regulatory improvement changes included in the final rule, such as the expanded scope of changes which can be made to design certification rules under § 52.63(a)(1).

The Commission also does not agree with commenters that the final rule's technical provisions should not be applied to applications for standard design certifications that have not yet been adopted by the Commission at the time of the issuance of this final rule. The Commission's longstanding requirement in Part 52 is that design certifications must meet the Commission's requirements in effect at the time of issuance of the final design certification rule. The Commission's practice in implementing this regulatory requirement is a two-part process of: (i) including an exemption from the new requirement in the final design certification rule, and (ii) establishing an "applicable regulation" in the final design certification rule that function in lieu of the exempted regulation. See Section V., "Applicable Regulations," in Appendices A-D of Part 52. This approach was developed by the NRC with public comment from various stakeholders, including each of the applicants for the design certification and NEI. The commenters provided no basis for departing from this past practice.

The Commission also disagrees with commenters that the early site permit applicants currently under consideration by the NRC, should not have to meet any applicable new requirements in the final rule. Former § 52.24 - by failing to specify a “cut-off date” for the applicability of Commission requirements - requires that early site permits meet the regulations in effect and applicable at the time of issuance of the early site permit. This is also true for design certifications under Part 52, as well as construction permits under Part 50. The Backfit Rule, 10 CFR 50.103, is consistent with this interpretation inasmuch as backfitting protections come into effect only upon issuance of the construction permit, see § 50.103(a)(1)(I). As a practical matter, virtually all of the provisions in the March 2006 proposed rule were applied to the current early site permit applicants in the review process. Therefore, there should be little impact on these applicants, and likely to be no need for the NRC to grant exemptions from the final Part 52 rule when issuing the ESPs to these applicants.

The Commission does not believe that a combined license applicant referencing either an early site permit or standard design certification rule could be required to meet new requirements within the scope of the early site permit or design certification, except as provided in relevant the finality provisions, §§ 52.39 and 52.63. Furthermore, the Commission has added a new regulatory provision, § 52.98, governing finality in Subpart C governing combined licenses, which reinforces the finality provisions in §§ 52.39 and 52.63. None of the commenters addressed why these regulatory provisions are insufficient to provide the necessary level of regulatory stability. Furthermore, one commenter’s (NEI) proposed rule language (NEI Comment, p. 15) establishes change restrictions for design certifications which is not only inconsistent with the pre-existing change restrictions in Part 52, but also is entirely inconsistent with that commenter’s separate proposal (NEI Comment, p. 20) to expand the scope of changes that may be made to design certifications.

In sum, the rulemaking provisions cited above, together with this comment response, provides future combined license applicants with regulatory stability and predictability in this area. Accordingly, for the reasons discussed above, the Commission has not included a “grandfather clause” in the final rule.

PRA Requirements Throughout Part 52

Comment 007-1: Several commenters stated that the proposed rule does not justify the requirements listed in proposed §§ 52.47(b)(1), 52.80(a), 52.137(b)(1), and 52.158(a), which would require applicants to submit a probabilistic risk assessment (PRA) as part of their applications.

The commenter suggested that applicants should not be required to submit their complete design-specific or plant-specific PRA. Instead applicants should only be required to provide a summary description of results, insights, and methodologies of their PRA in their final safety analysis report (FSAR). The complete PRA (e.g., codes) would be available for NRC inspection at the applicant’s offices.

The commenters also stated that they understand that it is not the NRC’s intent to require submission of the complete PRA based on discussions with the NRC staff during a March 14, 2006, workshop (Tr. 115-116). The commenters noted that Section 4.4 of draft NEI 04-01, *Industry Guideline for Combined License (COL) Applicants Under Part 52, Revision E* (October

2005), states that the design PRA for the referenced standard design is expected to serve as the plant-specific PRA to support a COL application. Chapter 19 of COL FSARs will provide information that demonstrates that a referenced design certification PRA bounds site- and plant-specific information, including an evaluation of unbounded site- and plant-specific information to determine that any differences have no significant impact on design PRA insights/results/methodologies. The commenters stated that re-submittal of extensive design PRA information (e.g., logic models, etc.) or the complete PRA as part of the COLA is not necessary as this information was reviewed and approved in connection with the design certification.

The commenters suggested that updated, plant-specific PRA analyses should be developed to support a COLA (1) if necessary to reflect and assess significant differences between plant-specific information and that assumed in the design PRA, (2) if needed to support a risk-informed departure or exemption from the design certification or other NRC requirement, or (3) if needed to support risk-informed design or operational requirements (e.g., 10 CFR 50.69 or NFPA-805). The commenters noted that maintaining such updated plant-specific PRA analyses available for NRC inspection (i.e., COL applicants would not need to submit this information with their COL applications) would be consistent with current practice for design certification and for operating plants.

The commenters noted that the plant-specific PRA that supports the COL application would be updated as plant-specific design and as-built information is developed during construction. This update will be consistent with PRA scope and quality standards in effect six months before the COL is issued. In this way, an updated plant-specific PRA that is representative of the as-built plant will be completed and available prior to fuel load to support plant operations.

The commenters noted that in addition, proposed § 52.80(a) would require a COL applicant that references a design certification, standard design, or manufacturing license to update the referenced PRA to account for “any design changes, departures, or variances.” The commenters stated that this provision could be misconstrued as requiring the updated PRA to address all design changes, including changes that are not relevant to the PRA. The commenters understand that the NRC agrees that the intent of this provision is only to require the updated PRA to account for design changes that are relevant to the PRA.

The commenters suggested that the FSAR Chapter 19 summary description of the PRA would satisfy the above § 52.80(a) requirement for COLA. The commenters expect that guidance regarding the Chapter 19 PRA summary description will be developed as part of the guidance in DG-1145, COL Applications for Nuclear Power Plants (LWR Edition), currently under development by the NRC staff.

NRC Response: The NRC agrees that applicants should not be required to submit their complete design-specific or plant-specific PRA and that, instead, applicants should only be required to provide a summary description of the PRA and its results (PRA information) in their final safety analysis report (FSAR) with the understanding that the complete PRA (e.g., codes) would be available for NRC inspection at the applicant's offices. The NRC has modified the final rule in several places to reflect this understanding, namely in §§ 52.47, 52.79, 52.80, 52.137, 52.157, and 52.158. The NRC expects that final rule §§ 52.79(a)(38) and 52.79(a)(46) will be addressed in a COL applicant's FSAR, Chapter 19. Consistent with Commission direction in the SRM on SECY-05-0203 (ML060300640), the details regarding scope and

methods acceptable to meet these requirements are to be addressed in regulatory guidance. Draft regulatory guide DG-1145 provides specific guidance for what a COL applicant should include in its FSAR, including Chapter 19 that addresses the applicant's plant-specific PRA and severe accident evaluations. The staff believes that the guidance provided in DG-1145 for the contents of Chapter 19 is consistent with the industry comment in that the staff does not expect the complete PRA to be included in the COL applicant's FSAR. Instead, the guidance is oriented towards the qualitative description of the PRA and its results, etc. In the case where a COL application is referencing a design certification, the NRC only expects the design changes and differences in the modeling (or its uses) pertinent to the PRA information to be addressed to meet the submittal requirement of § 52.79(d)(1). For COL applicants that do not reference a certified design, it will be necessary for the applicant to provide plant-specific PRA information for the entire plant.

New Requirements for Severe Accident Information

Comments 005-8 and 007-2(a): Proposed §§ 52.47(a)(20), 52.79(a)(38), 52.137(a)(20) and 52.157(j) would require applications for design certification, COLs, design approvals and manufacturing licenses to include a description and analysis of design features for the prevention and mitigation of severe accidents (core-melt accidents), including challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen detonation, and containment bypass. The commenters stated that the Supplementary Information for the proposed rule does not explain the basis for this proposed change, nor does it justify the change. Commenters believe that the proposed new requirement is inappropriate and unwarranted, and that NRC's existing guidance adequately addresses the need to discuss severe accident features in applications for new nuclear plants. The existing design certifications, which include a description and analysis of severe accident mitigation features as appropriate, provide ample evidence of this. The commenters stated that there is no reason to elevate existing guidance to the status of a regulation.

The commenters also stated that the proposal introduces severe accident design information requirements "in a manner that implies 'incorrectly' that severe accidents are part of the design bases, as defined in 10 CFR 50.2." Commenters stated that there is no explanation or basis provided for treating severe accident design requirements as part of the plant's § 50.2 design basis and that, in particular, it would be inappropriate to apply all of the typical design basis accident requirements (e.g., single failure requirements, quality assurance requirements, environmental qualification requirements) to severe accidents. The commenters understand that it is not the NRC's intent to require plants to apply design basis requirements to severe accident features. At the very least, commenters suggested that the proposed rule should be clarified to indicate that an applicant need not apply design basis requirements to severe accident features or analyses.

NRC Response: The Commission does not agree with the comment. First of all, the requirements for severe accident design information for future plants are not new and have been in place since issuance of the Commission's SRMs on SECY-90-016 and SECY-93-087. These requirements are included in the contents of applications for design certifications, combined licenses, design approvals, and manufacturing licenses for completeness and accuracy. Also, as noted by the commenter, the information was provided in previous design

certification applications. The inclusion of this requirement is consistent with the overall philosophy of this rulemaking, which is to clarify the licensing processes in 10 CFR Part 52.

Second, the commenter incorrectly asserts that design basis information, as defined in 10 CFR 50.2, must meet design basis accident (DBA) requirements, e.g., single failure, quality assurance, and environmental qualification. This assertion is clearly wrong and there is a lot of design information in a final safety analysis report (FSAR) that constitutes part of the plant's design basis but is not required to meet DBA requirements, e.g., the severe accident design features do not have to meet DBA requirements, as stated in SECY-90-016 and SECY-93-087. This clarification will be described in the section-by-section discussion. However, the severe accident design features must be described in the FSAR and will be part of the plant's design basis consistent with the definition in § 50.2 and past practice.

Comment 007-2(b): A commenter stated that even if these proposed requirements were not construed to be design bases requirements, severe accident requirements should not be imposed as broad generic requirements without extensive interactions with stakeholders to determine the ramifications and propriety of doing so. For example, the commenter noted that the proposed severe accident requirements are not appropriate for all reactor types. In particular, the commenter stated that such requirements should not be imposed upon gas cooled reactors, which are not susceptible to events such as steam explosions, high-pressure core melt ejection, and hydrogen detonation. Therefore, at the very least, the commenter suggested that the proposed provision should be modified to limit its applicability to light water reactors.

NRC Response: The Commission agrees that the requirements in its SRMs on SECY-90-016 and SECY-93-087 were developed for light-water reactor designs. Therefore, the requirement for providing a description and analysis of the design features in the contents of applications will be limited to light-water reactor designs.

Comment 007-2(c): A commenter noted that the proposed rule states that the application must provide a description and analysis of design features to "prevent" severe accidents. However, the focus of the proposed provision and all of the examples listed pertain to mitigation of severe accidents. Moreover, the commenter stated that the set of design features to "prevent" severe accidents is unbounded in the sense that the bulk of SSCs in a nuclear plant are designed to assure safe operation and prevent severe accidents. Therefore, the commenter suggested that the proposed rule should be modified to delete any reference to prevention of severe accidents.

Comment 005-9: The commenter stated that although the term "severe accident" is used in various places in the revisions to Part 51 and Part 52, the term is not defined in either of these rules, nor in Section 11 of the AEA. If the term is going to be used, the commenter stated that it should be clearly defined so there is no question about what constitutes a "severe accident." The commenter said that NRC should review the Commission's Severe Accident Policy Statement to ensure its definition of "severe accident" is consistent with past usage of the term.

NRC Response: The NRC recognizes that the term "severe accident" is used in many places throughout the regulations in Parts 51 and 52. However, the term is not consistently used in all of these requirements. Therefore, the reader needs to review the supplementary information in

the Federal Register Notice and other guidance documents for the specific explanation. An example is the severe accident change process in Section VIII.B.5.c of the design certification rules in Part 52. The supplementary information for these rules defines severe accidents for the purposes of that requirement.

New Requirements for Evaluation of Operating Experience

Comment 007-12: Several commenters noted that proposed 10 CFR§ 52.47(a)(19), 52.79(a)(37), 52.137(a)(19), and 52.157(p) would impose new requirements for applicants for a design certification, COL, manufacturing license, or standard design approval to address generic letters and bulletins issued up to six months before the docket date of the application, and comparable international operating experience. The commenters stated that the Supplementary Information for the proposed rule provides no justification for including a requirement to provide information on operating experience in Part 52 applications and that, in addition, no guidance is provided regarding the threshold or mechanism for consideration of operating experience. The commenters recommended that the NRC delete these proposed provisions.

The commenters noted that the Notice of Proposed Rulemaking (NPR) does reference the Staff Requirements Memorandum (SRM) dated February 15, 1991, as a basis for this proposed requirement. However the SRM simply states that applications should “incorporate the experience from operating events in current designs which we want to prevent in the future.” It does not require an evaluation of every NRC generic letter and bulletin, let alone international experience. The commenters stated that this is unnecessary because operating experience is reflected in other regulatory guidance that applicants are required to consider.

The commenters stated that the proposed requirement to address “comparable international experience” is vague, undefined, and unbounded, and that such a requirement could prove especially problematic in licensing hearings, since it could result in an applicant being forced to consider relatively trivial events identified by intervenors. Additionally, the commenters noted that to the extent that international experience is significant, presumably the NRC would take actions to communicate that experience in a generic letter or bulletin. See, e.g., NRC Generic Letter 97-01, “Degradation of Control Rod Drive Mechanism Nozzle and Other Vessel Closure Head Penetrations,” which discusses international experience with cracking in Alloy 600 vessel head penetrations.

NRC Response: The NRC disagrees with this comment. First of all, the NRC’s requirement to address operating experience insights is not new. This requirement was developed for future plants (see SRM on SECY-90-377 dated February 15, 1991) and it has been implemented in past design certification reviews by addressing NRC’s generic letters and bulletins. This past experience provides the necessary guidance for future applicants. Second, the NRC agrees that insights from generic letters and bulletins should be incorporated into the latest revision of the standard review plan and has revised this requirement accordingly. Finally, regarding the requirement to address comparable international operating experience, the NRC understands that some future applications may be for designs that are not based on or are not evolutions of plants that are operating in the United States. The NRC’s generic letters and bulletins may not provide operational insights for those non-U.S. designs. Therefore, the NRC expects those

applications to address how insights from any relevant international operating experience have been incorporated into their plant design.

The commenters stated that even without the requirement to address “comparable international experience,” the proposed requirements are unnecessary and unduly burdensome. The commenters noted that the NRC’s regulations already require an applicant to address the Standard Review Plan (SRP) in effect six months prior to submission of the application. The NRC is currently engaged in an extensive effort to revise and update the SRP, and the commenters understand and expect that update will include lessons learned from operating experience to the extent appropriate. Furthermore, the commenters stated that § 52.47 already requires design certification applicants to address unresolved safety issues and high and medium priority generic safety issues in NUREG-0933, and proposed § 52.79(a)(20) would require COL applicants to do the same. In sum, the commenters stated that the intent of the proposed new requirements to ensure consideration of operating experience, as appropriate, is already achieved by other proposed and existing NRC requirements.

NRC Response: The NRC does not agree that this requirement is unnecessary and unduly burdensome. Furthermore, unresolved safety issues and generic safety issues may not address all of the operational insights. However, as stated above, the NRC does agree that insights from generic letters and bulletins should be incorporated into the latest revision of the standard review plan and has revised this requirement accordingly.

The commenters also stated that the requirement to address all generic letters and bulletins is unduly burdensome. For example, the NRC has been issuing generic letters and bulletins since the 1970s. The commenters noted that in some cases, those generic letters and bulletins have been superseded by later generic letters and bulletins, other NRC guidance, or NRC regulations. The commenters stated that requiring applicants to address issues that are thirty years old and in some cases have been superseded by intervening developments is not a wise use of NRC or industry resources. Therefore, to the extent that NRC decides to retain a requirement to consider generic letters and bulletins, the commenters suggested that the requirement should be limited in time (e.g., to those generic letters and bulletins issued since the most recent revision of the applicable SRP sections).

NRC Response: The NRC agrees with this comment and, as stated above, has revised this requirement so that applicants only need to address operating experience insights from generic letters and bulletins issued after the most recent revision of the applicable standard review plan.

Comment 005-10: One commenter pointed out that in several places in Part 52 an applicant is required to provide “information necessary to demonstrate technical resolutions of those unresolved safety issues and medium- and high- priority generic safety issues.” This evaluation has been interpreted to include medium/high priority generic safety issues (GSIs), regardless of whether they have been resolved or not. The requirement to address “resolved” GSIs imposes a burden on an applicant with no associated benefit. Since new plant designs must comply with applicable regulatory requirements, they will, by definition, comply with the bases for resolution of previous GSIs. The commenter suggested that this requirement should be changed to cover only unresolved GSIs that are applicable to the design.

NRC Response: The NRC does not agree with this comment. The resolution of GSIs was determined based on current operating plants and those resolutions may not apply to future plants with new and different design features. The future applicants need to address how their plant design resolves each of the medium/high priority GSIs.

Comment 005-11: One commenter noted that in several places in Part 52 an applicant is required to show that operating experience has been taken into account in a new plant design, including “comparable international operating experience.” If the NRC becomes aware of international operating experience that it believes is relevant to one or more new plant designs, the NRC should identify that experience (e.g., by means of a generic letter) for consideration by an applicant. The current open-ended requirement should be deleted. If, however, the NRC determines international operating experience must be considered, the staff should be instructed to permit applicants to use relevant experience gained outside the United States to justify the use of new technologies in U.S. plants. Consideration of such information should include these “positive” aspects of international experience as well as the implied “negative” aspects of the current wording of the rule.

NRC Response: The NRC does not agree with this comment. As explained above, the portion of the requirement for international operating experience, only applies to nuclear plant designs that are not based on or are not evolutions of plants that are operating in the United States. The NRC’s generic letters may not address operational insights for those non-U.S. designs. Therefore, the NRC expects those applications to address how insights from any relevant international operating experience have been incorporated into their design.

Provisions Authorizing Open-ended Information Requirements

Comment 007-19: Several commenters noted that proposed 10 CFR§ 52.17(d), 52.79(a)(42), 52.137(a)(27) and 52.157(p) would allow the NRC to require applicants for an Early Site Permit (ESP) COL, standard design approval and manufacturing license to include “any information beyond” that specified in application requirements. The commenters stated that the proposed rule would establish an open-ended provision that essentially would confer upon the NRC staff the authority to set ad hoc requirements outside the rulemaking process. The commenters stated that such open-ended discretion on the part of the staff to require information beyond that specified in the regulation is inconsistent with the requirements of the Administrative Procedures Act and that the NOPR fails to justify these proposed new requirements.

The commenters stated that to the extent that additional information may be necessary during the NRC staff review of an application, the staff already has a “request for additional information” process that may be applied to Part 52 applications. This process is codified in 10 CFR 2.102(a). Furthermore, the commenters noted that the staff stated in its comments in its December 27, 2005, response to the Commission’s SRM, that the NRC “has inherent authority to require submission of additional information, upon a determination that it is necessary.” Thus, the commenters concluded that no additional regulatory authority is needed for the NRC staff to request additional information necessary to complete its review of an application.

The commenters suggested that these proposed requirements should be deleted. For the same reason, and because the NRC and the industry now have substantial experience with the design certification process, the similar requirement in existing § 52.47(a)(3) should be deleted.

NRC Response: The Commission disagrees with the commenter's suggestion that these provisions would confer upon the NRC staff the authority to require applicants to comply with either arbitrary and capricious information requests, or information requests on matters outside the regulatory purview of the NRC. No federal administrative agency has the authority to act in derogation of the Administrative Procedure Act or in excess of the powers delegated to it by Congress in applicable federal statutes. Nor does an agency possess the authority to adopt a regulation which effectively grants itself dispensation from compliance with applicable statutes.

Nonetheless, the Commission has decided that the disputed provisions in the proposed rule are unnecessary, because the NRC staff already possesses the authority under § 2.102(a) authority to require submission of necessary information. Accordingly, proposed § 52.17(d), § 52.47(a)(27)(same as § 52.47(a)(3) in the 1989 Part 52 rule), § 52.79(a)(42), § 52.137(a)(27), § 52.157(p) are not included in the final rule.

New Requirements for Applicants to Demonstrate Technical Qualifications

Comment 007-27: Several commenters noted that §§ 52.24(a)(4), 52.47(a)(23), 52.54(a)(4), 52.137(a)(23) and 2.104(d)(v) of the proposed rule would impose requirements for an ESP applicant, design approval applicant, and design certification applicant to demonstrate technical qualifications. The commenters stated that the Supplementary Information for the proposed rule neither explains nor justifies the purpose of these proposed provisions.

The commenters believe these proposed changes are inconsistent with the provisions in proposed 10 CFR 50.40 regarding technical qualifications for applicants. The commenters stated that “proposed § 50.40(b)—correctly—does not specify that an applicant for an early site permit, a design certification, or a design approval need demonstrate technical qualifications.” The commenters went on to state that these proposed amendments also appear inconsistent with Section 182.a of the Atomic Energy Act, which does not require that applicants for an ESP, design certification, or design approval demonstrate their technical qualifications; rather, the statute imposes that requirement only upon applicants for an NRC license.

The commenters stated further that if promulgated, these proposed changes would impose a new requirement on the applicants in question. The commenters noted that existing ESP applicants and design certification applicants were not required to demonstrate their technical qualifications. The commenters also noted that there does not appear to be a reason to impose such an additional requirement on future ESP and design certification applicants. The commenters stated that Industry is unaware of any problem here that the proposed new requirements are needed to resolve.

The commenters object to these additional requirements for ESP holders because they are not authorized to conduct any safety-related construction activities (see 10 CFR 52.25), and object to the additional requirements for design certification and design approval applicants for slightly different reasons. The commenters stated that a design certification is a rulemaking activity, not a license, and the design certification applicant will not necessarily be supplying a reactor to a future COL applicant. Instead, under 10 CFR 52.73, another entity may be the reactor vendor, and the COL applicant will need to demonstrate the technical qualifications of that entity (as well as its other primary contractors). Similarly, if the COL applicant references a standard design approval, it will need to demonstrate the technical qualifications of the vendor.

Thus, the commenters concluded that there is no reason for an applicant for an ESP, design certification, or design approval to demonstrate its technical qualifications at the time it submits its ESP application. Instead, the commenters suggested that the COL applicant will need to demonstrate its technical qualifications and those of its reactor vendor. The commenters believe that deferral of such a demonstration until the COL stage is especially appropriate, since the technical qualifications of the vendor and ESP holder may change substantially during the 15- to 20-year interval between the issuance of the ESP and/or design approval and the submission of the COL application.

The commenters recommended that the NRC delete the proposed requirement in §§ 52.24(a)(4), 52.47(a)(23), 52.54(a)(4), 52.137(a)(23) and 2.104(d)(v) discussed above. At a minimum, the commenters suggested that proposed § 52.24(a)(4) and 2.104(d)(v) requirements pertaining to ESP applicants should be deleted.

NRC Response: The NRC disagrees with this comment. Although the NRC agrees that the AEA imposes the technical qualification finding specifically for license applicants, it does not preclude the NRC from a determination that such a finding is also necessary in other contexts. The application for an ESP, design approval, or design certification may become part of a COL application, if referenced, and the applicant will create information that may become the bases for a future license. Therefore, the applicant must be qualified to perform design, analyses, safety determinations, and siting determinations. Accordingly, the NRC has concluded that a technical qualification finding needs to be made for these

New Requirements for Control of Radioactive Effluents

Comment 007-32: Several commenters noted that proposed §§ 52.47(a)(9) and (a)(10) and §§ 52.137(a)(9) and (a)(10) would require a design certification or standard design applicant to (1) describe the kinds and quantities of radioactive materials expected to be produced and used in the construction and operation and the design features for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR Part 20, and (2) provide information on the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations described in 10 CFR 50.34a(e). The commenters stated that currently, 10 CFR 50.34(b)(3) requires that an application for an operating license include information in the FSAR that addresses the “kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in Part 20 of this chapter.” The § 50.34(a) requirements for a construction permit application do not contain a corresponding requirement for radioactive materials produced during construction. The NRC proposes no changes to the provisions in §§ 50.34(a) or (b).

The commenters noted that the proposed changes would also tailor the current Part 50 requirements for design certifications and design approvals by requiring that applications describe design features (rather than “means”) for controlling and limiting radioactive effluents and radiation exposures. Based upon comments made by the NRC at the workshop on March 14, 2006 (Tr. 152-153), the commenters understood that by this change, the NRC staff did not intend to impose different effluent requirements on applicants for design certification and design approvals than on other applicants. Rather, the commenters understood that NRC’s intent was to make clear that design certification and design approval applicants would

not be expected to describe “means” for controlling and limiting effluents that are outside the scope of the standard design (e.g., procedural controls, training, etc.). Nevertheless, the commenters believe that the language in the proposed rule might be construed otherwise. To avoid any implication that a new requirement is being imposed upon applicants for a design certification or standard design, the commenters suggested that the proposed amendments should be modified as discussed below.

The commenters suggested that the changes would impose new requirements for controlling effluents during both construction and operation (only operation is included in the current Part 50 requirements), and that no basis was provided for adding requirements on the construction phase, and doing so would be inconsistent with existing requirements in § 50.34(a) and proposed § 52.79(a)(3). The commenters suggested that proposed §§ 52.47(a)(9) and 52.137(a)(9) should be modified consistent with existing requirements.

Furthermore, the commenters believe that the “proposed rule is not internally consistent.” The commenters noted that proposed changes to 10 CFR Part 50, Appendix I, state that §§ 52.47 and 52.137 provide that applications for design certification and design approval “shall include a description of the equipment and procedures for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems.” The commenters suggested that the proposed change to Appendix I should be modified to be consistent with §§ 52.47(a)(10) and 52.137(a)(10).

NRC Response: Although the NRC does not agree that proposed §§ 52.47(a)(9) and 52.137(a)(9) would impose new requirements on controlling effluents, the final rule language in §§ 52.47(a)(5) and 52.137(a)(5) have been revised to be consistent with the language in § 50.34(b)(3). As explained by the NRC at the workshop on March 14, 2006, the focus of the review for design approvals and design certifications will be on the design features used for controlling radioactive effluents. The procedures for control of radioactive effluents will be reviewed as part of the combined license application.

New Requirements for an Applicant for an ESP of Design Certification to Describe its Quality Assurance (QA) Program

Comment 007-37: Several commenters noted that proposed Section 50.55(f) would impose requirements on the quality assurance program, as described or referenced in the safety analysis report, on holders of an ESP, a manufacturing license, or a combined license (up to issuance of the § 52.103(g) finding, when the requirements of 10 CFR 50.54(a) would apply). The commenters also noted that §§ 52.17(a)(1)(xii), 52.47(a)(21), 52.137(a)(21), 52.157(e)(17) and Appendix B to Part 50 in the proposed rule would impose a new requirement on an ESP applicant, a design certification applicant, an applicant for design approval, and an applicant for a manufacturing license to describe the quality assurance program under Appendix B to Part 50 for ESP site activities, design activities, and manufacturing activities respectively.

The commenters stated that as written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program. The commenters did not believe that it was the intent of the NRC to apply the Appendix B requirements so broadly. Therefore, the commenters recommended that the NRC revise these provisions to clarify that the Appendix B QA program would apply only to activities affecting the

safety-related functions of the structures, systems, and components (SSCs), and not to all ESP site activities, design activities, and construction activities. The commenters' recommended changes would make the new Part 52 requirements consistent with existing Appendix B, which states, "The pertinent [QA] requirements of this appendix apply to all activities affecting the safety-related functions [of SSCs]."

Additionally, the commenters also stated that these proposals could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B. However, the commenters stated that not all of those criteria are applicable to each of the applicants. The commenters noted as examples that Criterion III on design control, Criterion IX on special processes, and some of the other criteria are clearly inapplicable to ESP applicants. According to the commenters, Criterion IX, Criterion X on inspections, and some of the other criteria would also not be applicable to applicants for design certification and design approval. The commenters did not believe that it was NRC's intent to apply the Appendix B requirements so broadly. Therefore, the commenters recommended that the NRC modify the language in the proposed rule to clarify that the applicant need only establish and implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant.

Comment 007-38: Several commenters noted that proposed § 50.55(f) would impose requirements on the quality assurance (QA) program, as described or referenced in the safety analysis report, on holders of an ESP, a manufacturing license, or a COL (up to issuance of the § 52.103(g) finding, when the requirements of 10 CFR 50.54(a) would apply). The commenters also noted that §§ 52.17(a)(1)(xii), 52.47(a)(21), 52.137(a)(21), 52.157(e)(17), and Appendix B to Part 50 in the proposed rule would impose a new requirement on an ESP applicant, a design certification applicant, an applicant for design approval, and an applicant for a manufacturing license to describe the QA program under Appendix B to Part 50 for ESP site activities, design activities, and manufacturing activities respectively.

The commenters noted that proposed § 52.17(a)(1)(xii) would require an ESP applicant to provide "a description of the quality assurance program applied to site-related activities for the future design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site." The commenters stated that this provision is ambiguous and could be incorrectly interpreted as applying to all site-related activities. Furthermore, the commenters stated that on its face, this language would require a QA program for an ESP to have a broader scope than a QA program for a CP or COL. The commenters stated that "no justification has been provided for this expansion of the scope of the ESP QA program" and that "such an expansion is unwarranted." The commenters stated that the scope of an ESP QA program should be no greater than the scope of a QA program for a CP or COL.

NRC Response: The NRC does not agree that, as written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program, as opposed to applying only to activities affecting the safety-related functions of the structures, systems, and components. The commenter quoted the following words from the existing language in Appendix B, "The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components,"

[emphasis added], as evidence that the existing requirements relate only to safety-related SSCs. These words have not been removed from Appendix B and therefore apply to all of the new Appendix B requirements for ESPs, design certifications, design approvals, and manufacturing licenses. The NRC notes that the requirements in the current versions of §§ 50.34(a)(7) and 50.55(f) applicable to construction permits do not contain qualifiers that the Appendix B QA requirements apply only to activities affecting safety-related SSCs because such a qualifier is unnecessary given the language in Appendix B to Part 50. In creating parallel requirements for the Part 52 licensing and approval processes, the NRC tried to be as consistent as possible with the existing requirements for Part 50 applicants and licensees.

NEI also commented that some of the proposed language regarding QA requirements could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B and noted that not all of those criteria are applicable to each of the applicants.

The NRC does not agree that the proposed rule language regarding QA requirements for an ESP, design certification, design approval, or manufacturing license needs to be modified. Each of the subject provisions (52.17, 52.47, 52.137, and 52.157) states that the description of the quality assurance program must include a discussion of how the applicable requirements of Appendix B will be satisfied [emphasis added]. Therefore, the NRC believes it is clear that it was not the intent to apply the Appendix B requirements too broadly and that the language in the proposed rule is sufficient to indicate that the applicant need only implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant. Therefore, no changes have been made to these sections in the final rule.

Note that on July 19, 2006, the commenter (NEI) informed the NRC by e-mail (ML062710327) that it could not recreate the basis for some of the words in its May 30, 2006 recommended language for 52.17(a)(i)(xii) and that, for purposes of dispositioning this comment, the NRC should ignore them.

Deletion of the Option of Using Appendix Q and Subpart F by COL Applicants

Comment 007-43: Several commenters noted that the propose rule would delete 10 CFR Part 52, Appendix Q, which allows a Part 52 applicant to request early site suitability review. In addition, the commenters noted that the proposed rule would not clarify that Subpart F of 10 CFR Part 2 may be used by COL applicants. The commenters stated that while no applicant has yet expressed an intent to use the early site review process in Appendix Q or the process in Subpart F to Part 2 for partial decisions on site suitability issues, that these processes may provide important flexibility for early and efficient consideration of site suitability issues for COL applicants. The commenters asserted that there is no reason to eliminate this flexibility, and no harm is caused by allowing Part 52 applicants to utilize these provisions, therefore the commenters recommended that the NRC retain Appendix Q in Part 52, as well as in Part 50.

The commenters noted that both of these regulations allow critical path site issues to be reviewed by NRC in advance of the submission of a COL application (COLA), in cases where the applicant's schedule or other considerations do not allow it to complete the ESP process in advance of the COLA. Further, the commenters stated that utilization of Appendix Q or

Subpart F in the context of a COLA could allow the NRC staff to more efficiently utilize its resources to focus early review of site issues only on those issues sought by the applicant, rather than the full scope of issues required by an application for an ESP.

The commenters noted that in the August 2005 draft of the proposed rule, the NRC indicated changes in 10 CFR Part 2 Subpart F that would have allowed the Subpart to be used in the Part 52 COL process. The commenters stated that this change was not part of the proposed rule. Thus, the commenters concluded, "one could (erroneously) conclude that Part 2, Subpart F, is only applicable to the Part 50 construction permit process." The commenters suggested that the August 2005 draft revisions to Subpart F be incorporated into the final Part 52 rule to clarify its continuing availability to Part 52 applicants.

The commenters recommended changes that they assert would specifically allow an application for an ESP or COL to reference a review conducted in accordance with Appendix Q to Part 50. The commenters believe that their recommended changes would also modify the provisions in Subpart F of Part 2 explicitly to allow its use in Part 52 actions. Based upon the statements provided by the NRC at the workshop on March 14, 2006 (Tr. 23-24), the commenters understood that it was the NRC's intent to allow Part 52 applicants to use Subpart F.

NRC Response: In response to commenters concerns, the NRC has decided not to remove Appendix Q from Part 52 in the final rule. Appendix Q has been included in Part 52 in the final rule and conforming changes have been made to make it available for use by prospective early site permits and combined license applicants. Such applicants will have the same option for early resolution of site suitability issues as is currently available to construction permit applicants. This will provide early site permit and combined license applicants with additional flexibility to seek early resolution of issues.

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

The Requirement to Evaluate Applications Against the SRP Should Only Apply to Light Water Reactors

Comments 007-63 and 007-79: Several commenters noted that proposed §§ 52.47(a)(26), 52.137(a)(26), and 52.157(p) state that a design certification, design approval, and manufacturing license application shall include an evaluation of the standard plant design against the SRP in effect 6 months prior to the docket date of the application.

The commenters noted that these proposed provisions are similar to 10 CFR 50.34(h). However, the commenters stated that unlike § 50.34(h), the provisions in the proposed sections are not limited to applicants for light-water reactors (LWRs). The commenters suggested that

this may have been an inadvertent oversight by the NRC. The commenters noted that “the analogous provision for COL applicants, § 52.79(a)(1)(41), correctly limits this requirement to LWRs.”

The commenters suggested that, similar to the requirement in § 50.34(h), the requirement in proposed §§ 52.47(a)(26), 52.137(a)(26), and 52.157(p) should be explicitly limited to LWRs. The commenters continued that since the SRP was developed solely for light water reactors, “it would be inappropriate and serve no useful purpose to require design certification applicants for other types of reactors (e.g., high-temperature gas cooled reactors) to evaluate their design against the SRP.”

NRC Response: The NRC agrees with the commenters and revised the subject provisions to be applicable to light-water cooled nuclear power plants. However, the NRC disagrees with the commenters that applicants for non-LWR designs, such as the PBMR, should not be required to evaluate their designs against the SRP. First, there are a large number of areas within the SRP that are “technology-neutral” in the sense that the SRP applies regardless of the technology of the reactor under review. Most of the requirements in Part 50 are, for the most part, technology neutral, and have been applied in past AEC/NRC licensing actions for non-LWR designs, such as Peach Bottom, Fort St. Vrain, and the Clinch River Breeder Reactor. At least one potential combined license applicant (Exelon) has concluded that most of the technical requirements in Part 50 would be applicable to non-LWR designs that they were considering for a new nuclear power plant. Each of the current standard design certification applicants identified several technical requirements which they believed are not technically applicable to their design. The Commission provided dispensation from compliance with these requirements by including appropriate exemptions in each of final design certification rules. The same process may be used by future applicants for design certifications, including applicants for certification of non-LWR designs.

Second, the SRP is not a requirement, and indeed, the regulation simply requires the applicant to identify where the design has diverged from the guidance in the SRP. The purpose of the SRP evaluation requirement is one of resources and planning: it allows the NRC staff to estimate application review areas which may require special resources, and a greater period of time to perform the safety review. The commenter did not set forth more specific reasons why the underlying goals of the requirement for evaluation against the SRP would not be served in the case on non-LWR designs. See Section V.C.8.f of supplementary information for more discussion on this requirement.

Support for Conforming Changes and Other Beneficial Proposals

Comments 007-70 and 007-79: Several commenters suggested one additional change to Part 52 that it and its constituents consider necessary to ensure that the regulations are consistent and conform to the Energy Policy Act of 2005 and previous rulemakings. The commenters suggested that the NRC include changes to the design certification rules and the change processes in Part 52 to be consistent with the concepts of the revised 10 CFR 50.59. The commenters noted that the NRC deferred these changes from the § 50.59 rule change. [See 64 FR 53582, 53601, October 4, 1999] The commenters believe that the proposed rule adequately addresses this issue. Several commenters also stated that the industry considers the changes in the NOPR in Appendix A, B, and C to Part 52, regarding identified corrections to

design certification rules, such as to Section X, Records and Reporting, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.3.1 General Provisions

Expansion of the Applicability of Requirements for Employee Protection

Comment 007-17: Several commenters noted that proposed 10 CFR § 52.5(a) would prohibit discrimination by a Commission licensee, holder of a standard design approval, an applicant for a license, standard design certification, or standard design approval, a contractor or subcontractor of a Commission licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, against an employee for engaging in certain protected activities. The commenters also noted that proposed changes to Part 19 (especially proposed 10 CFR § 19.20) includes parallel provisions.

The commenters stated that application of employee protection requirements to design certification applicants and applicants for design approval “is inappropriate and unauthorized under Section 211 of the Energy Reorganization Act (the Act).” The commenters noted that Section 211 of the Act applies to “employers,” and that the Act defines “employer” as including an NRC licensee or applicant for license, and contractors or subcontractors of such a licensee or applicant, and certain Department of Energy contractors or subcontractors. The commenters stated that an applicant for a design certification or design approval is not encompassed within any of the provisions in Section 211.

The commenters further stated that an applicant for design certification is fundamentally different from an applicant for a license. The commenters stated that design certification occurs through rulemaking, and as a result, a design certification applicant has no proprietary interest in a design certification. The commenters noted that as indicated by provisions such as 10 CFR 52.73, a design certification can be utilized by any qualified vendor, and the design certification applicant will not necessarily be the ultimate designer or supplier of a plant that references the design certification. The commenters concluded that it would therefore be inappropriate to apply the provisions in proposed § 52.5 to design certification applicants.

The commenters stated that the proposed rule would have the effect of applying licensing provisions to design certification rulemaking. The commenters concluded that this is a fundamental shift in the nature of design certification that “is inappropriate, is unfair to design certification applicants, and should be rejected.”

The commenters finished by stating that if the NRC does not agree, the proposed revision should at least be modified to mitigate some of the detrimental features. In particular, the commenters suggested that at most, § 52.5(a) should apply only during those periods in which the applicant for design certification or design approval is actively engaged in regulated activities. The commenters also recommended that parallel changes be made in proposed 10 CFR Part 19.

NRC Response: The NRC disagrees with the comment that application of employee protection requirements to design certification applicants and applicants for design approval “is inappropriate and unauthorized under Section 211 of the Energy Reorganization Act (the Act). As stated in the Supplementary Information section of the proposed rule, the NRC believes that its regulatory authority under Section 211 and Section 401 of the 1974 ERA is much broader than the current scope of Part 19. The anti-discrimination proscriptions in Section 211 of the ERA apply to any “employer,” which the NRC regards as including non-licensee entities otherwise regulated by the NRC, such as applicants for and holders of standard design approvals, and applicants for standard design certifications. The Commission believes that the use of the term, “includes,” in paragraph (a)(2) of Section 211 of the 1974 ERA was not intended to be an exclusive list of the persons and entities subject to the anti-discrimination provisions in that section. The House Report on H.R. 776, which was adopted by Congress as the Energy Policy Act of 1992, states:

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

H.Rep. No. 102-474, Part 8, 102d Congress, 2d Sess., at 78-79 (1992) (emphasis added). There was no discussion of the statutory language in the conference report. H.R. Conf. Rep. No.102-1018, 102d Cong., 2d Sess. (1992). Commenters did not provide any reason why the Commission’s interpretation of “includes” is incorrect. The Commission’s interpretation is reasonable because design certifications and design approvals help to form the basis for NRC safety determinations with respect to licensing of nuclear power plants referencing the design certifications or design approvals. Accordingly, in the absence of any showing that the Commission’s interpretation is incorrect or otherwise unreasonable, the NRC rejects the comments and has made no changes in the final rule. The NRC also does not agree with the commenters’ suggestion that § 52.5(a) should apply only during those periods in which the applicant for design certification or design approval is actively engaged in regulated activities. The NRC believes that employees should be able to raise safety concerns related to a design approval or design certification at any time without fear of retaliation.

Beneficial Changes Proposed for Part 52

Comment 007-74: Several commenters stated that the industry considers the changes in the NOPR in § 52.1, regarding definitions, and in § 52.7, regarding the applicability of the § 50.12 exemption process, to be beneficial . The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.3.2 Subpart A - ESP

Loss of “Finality” for Environmental Issues

Comments 002-1, 002-2, 002-5, 010-1, 012-1, 006, 009, and 013:² Several commenters expressed concerns about the loss of finality previously awarded to safety and environmental issues addressed in an ESP, specifically that issues addressed in an ESP would no longer be treated as resolved in subsequent COLs. Commenters stated that specific language in proposed §§ 51.50(c)(1)(iii), 51.107(b)(3) and 52.39(a)(2)(v) was contrary to the ESP finality principle of existing Part 52 (54 FR 15372, 15373, 1989). Commenters believed that the NRC should not eliminate current §§ 52.39(a)(2), 52.79(a)(1), and 52.89 with respect to previously resolved environmental issues, and should not promulgate proposed §§ 52.39(c)(1)(v) and 51.107(b)(3) as written. These commenters stated that the changes would, if implemented, lead to unnecessary and inefficient reconsideration, re-review, and possible re-litigation of issues that had been resolved in an ESP proceeding, and could deter future use of the ESP process. Commenters expressed concern that if enacted, the proposed amendments would allow, as long as the pleading standards were met, any intervenor to litigate a previously evaluated environmental issue by alleging that new information existed which altered the prior conclusions. (71 FR 12826) Commenters expressed concern that NRC staff had suggested that to allow a realization of prior ESP findings, a COL applicant referencing an ESP would be required to update its previous environmental report to present and analyze final plant design information, regardless of whether it fell within the bounds of the prior evaluation. Commenters expressed support for current rules that avoided reconsideration of environmental issues in a COL application when those issues had previously been assessed and resolved in an ESP proceeding.

One commenter suggested the NRC should provide direction to the NRC staff that it is not necessary for the staff to examine or revalidate previously resolved environmental issues, or perform an independent search for new information. The commenter stated that where environmental impacts were evaluated at the ESP stage, any supplemental EIS at the COL stage should be limited only to those matters requiring supplementation. The commenter further noted that the NRC staff should rely upon comments from the public and consulting agencies to identify any areas where supplementation might be needed. The commenter stated that if no person identified a need to supplement the discussion of an impact addressed in the ESP EIS, there should be no need for any discussion of that impact in the EIS supplement at the COL stage.

NRC Response: The NRC agrees in part with the commenters. Upon further consideration of the proposed rule language and discussions with stakeholders in NRC public meetings, the NRC agrees that the rule language in §§ 51.50(c)(1), 51.107(b)(3) and 52.39(a)(2)(v) should be modified to more clearly reflect the finality of environmental issues resolved in an ESP. However, the NRC does not agree that it should retain the rule language in current

²Commenters 006, 009, 010, 012, and 013 also fully endorsed and supported NEI's comments submitted on May 16, 2006. Therefore, all of these commenters are included in each of NEI's May 16, 2006 comments (comment number 002). For simplicity, these comment numbers are not repeated in this document for each comment.

§§ 52.39(a)(2), 52.79(a)(2), and 52.89 because it did not appropriately reflect the NRC's obligations under NEPA.

Instead, the final rule limits, in § 52.39(c)(1)(v), environmental contentions that may be litigated to any significant environmental issue related to the impacts of construction and operation of the facility that was not previously resolved in the proceeding on the early site permit application, or any issue involving the impacts of construction and operation of the facility that was previously resolved in the proceeding on the early site permit application for which significant new information has been identified. The NRC believes that its regulations and the applicable case law interpreting the National Environment Policy Act of 1969, as amended (NEPA), allow the NRC to incorporate the ESP EIS by reference in the combined license EIS. However, the NRC must address identify any significant new information for issues that were resolved in the ESP EIS. For these reasons, the NRC believes the final rule language appropriately captures the agency's NEPA obligations.

For similar reasons, the NRC does not agree that it should rely upon comments from the public and consulting agencies to identify any areas where supplementation of an ESP EIS might be needed at the COL stage and that, if no person identified a need to supplement the discussion of an impact addressed in the ESP EIS, there should be no need for any discussion of that impact in the EIS supplement at the COL stage. Instead, the NRC has revised § 51.50(c) in the final rule to require a combined license application that references an early site permit to contain any significant new information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding and a description of the process used to identify new and significant information regarding the NRC's conclusions in the early site permit environmental impact statement. While the NRC is ultimately responsible for completing any required NEPA review, the combined license applicant must identify whether there is new and significant information on a previously resolved issue. A combined license applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form for issues for which the combined license applicant does not identify any new and significant information. The NRC believes that the final rule language in § 52.39 and Part 51 appropriately captures the agency's NEPA obligations.

Comment 005-14: A commenter questioned whether there are limitations on the NRC's ability to evaluate and "inquire into the continued validity" of the information supporting an environmental impact statement for an ESP.

NRC Response: Upon further consideration, the NRC has removed this language from the Supplementary Information section of the final rule because it implied a overly broad view of the NRC's obligations under NEPA for the review of a COL application referencing an ESP.

Petitions for Waiver of Finality Rule

Comments 002-9, 002-11, 002-12, 002-13, 002-14, 002-15, 002-16, 002-95: Commenters believed the NRC should modify the final rule to reflect that persons seeking to reopen previously resolved environmental issues in a COL proceeding must petition the NRC for a waiver of the finality rules (currently, 10 CFR§ 52.39(a)(2), 52.79(a)(1), and 52.89). They

argued that if the applicant, the NRC staff, or a member of the public identified new information that they believed altered the evaluation of an environmental issue addressed in the ESP EIS, and if this new information did not relate to a design feature exceeding the parameters specified in the ESP, then a waiver of the finality rules should be obtained from the NRC in order to allow reconsideration of the previously analyzed impact. Commenters stated that consistent with federal case law on when an agency must prepare a supplement to an EIS, the NRC should grant the waiver only if the new information presented a “seriously different picture of the environmental impact” of granting a COL than what was previously envisioned. (*S. Trenton Residents*, 176 F.3d at 663; *New River*, 373 F.3d at 1330). Commenters stated that in accordance with the NRC’s Rules of Practice, the NRC should be able to grant a waiver request only if it were supported by an affidavit establishing the special circumstances with particularity and making a prima facie showing that the rule should be waived. (10 C.F.R. § 2.335(b),(c)). They described these procedural safeguards as needed and appropriate to preserve the current rule’s objective of allowing early resolution of environmental issues.

Furthermore, the commenters argued that the NRC’s consideration of the new information in the course of evaluating a waiver request would be consistent with federal case law that allows agencies to employ non-NEPA documentation (i.e., documentation aside from an EA or supplemental EIS and not subject to NEPA public participation requirements) to determine whether alleged new impacts are significant enough to require the preparation of supplemental NEPA documentation and explain why not.

Alternately, one commenter explained their support for the use of waivers as follows: “requiring a waiver would also be consistent with the approach that the NRC has followed in license renewal proceedings, where the NRC staff (or an intervenor) is required to apply to the Commission for a waiver before any Category 1 issue (i.e., any issue previously resolved generically) can be reconsidered, based on significant and new information. See SECY-93-032 at 3-4; 61 FR 28467, 28470 (1996). This approach would allow supplementation of the ESP EIS where appropriate, while maintaining the preclusive effect of the Part 52 regulations. In the Supplementary Information in the rulemaking notice, the NRC recognizes the applicability of the license renewal environmental review process to the review of COL applications referencing ESPs (71 FR 12826), and the commenters agree that the NRC’s license renewal approach is fully applicable here.”

NRC Response: The NRC does not agree with the commenters’ suggestion that persons seeking to reopen previously resolved environmental issues in a COL proceeding should be required to petition the NRC for a waiver of the finality rules. The Commission’s view is that an EIS prepared for a combined license referencing an ESP must address significant new information that affects the evaluation of an environmental issue resolved in the ESP EIS, but only if that environmental issue is relevant to the decision to issue the combined license. For example, information related only to siting that was resolved in the ESP proceeding is not relevant to the decision to issue the combined license, because the siting issue was finally determined, from both a safety and environmental standpoint, as part of the issuance of the ESP. By contrast, information which a public stakeholder claims is new and significant only with respect to the matters resolved in the early site permit proceeding will be addressed by the Commission as part of the routine scoping and public comment process. The Commission’s inquiry, with respect to such information, will be - as suggested by the commenters - directed at whether the information presents a “seriously different picture of the environmental impact,” or otherwise could reasonably lead to a different conclusion with respect to the underlying decision

to issue the ESP in its current form. The Commission will not, however, allow such matters to be addressed in the adjudicatory hearing for issuance of a combined license. Instead, they will be treated as petitions for modification of the early site permit under §52.39(c)(2). The petition will not be considered by the Commission unless the petitioner had raised this matter in either the scoping process or public comment process with as much detail and information as would otherwise be required to support the “basis requirement” for a contention in 10 CFR 2.309. This is essentially the same as the “waiver” process advocated by the commenters, and is based upon former § 52.39(a)(2)(iii).

With regard to the comparison with the license renewal process, for license renewal, the NRC performed the analysis of environmental effects during the renewal period for each of the operating plants; the NRC also had the benefit of the operating experience of over 100 units for an extended period of time to support its analyses. The analysis based on this information was codified and use of the waiver process to challenge this information was appropriate. For new plants where the environmental impacts of construction and operation were resolved in the ESP proceeding, the conclusions were based on analytical methods and assumptions regarding the design, construction and operation of the facility and some of the information about the design, construction practices, and proposed operations were not well known at the time of the ESP application. Therefore, it is not analogous to the license renewal situation.

Comments 011-3 and 011-4: A commenter noted that in § 52.39 (page 12783), in C.4.g, in the last paragraph, the proposed rule states the proposed revision will be in § 52.39(d), but the commenter suggests that it is actually in § 52.39(e). The commenter also noted that in C.4.g, and the reference rule sections, the text discusses requirements related to information requests with a focus on safety information. The commenter asked whether there is, or should be, an equivalent requirement for environmental information.

NRC Response: The NRC agrees that all references to this provision in § 52.39 should be to paragraph (e) and has made the correction in the final rule. The requirements in §52.39(e) are based on the requirements in current § 50.54(f). Section 50.54 addresses condition to be placed on licenses related to safety requirements. Section 50.54 does not address environmental conditions, which are addressed in § 50.36b. A provision similar to 50.54(f) does not currently exist for environmental conditions and the NRC did not propose to add one in this rulemaking.

Duplicative Review in Applications for ESPs or Design Certifications and COL Applications

Comment 012-11: A commenter stated that in order to promote efficiency and standardization, the NRC should include in any final rule a provision providing that if a COL application references a pending application for an ESP or design certification, the COL proceeding will not include duplicative review or litigation of issues being resolved in the other, referenced proceedings. The commenter stated that alternatively, if the NRC does not address this issue by rule, it should issue a policy statement providing appropriate guidance to the NRC staff and Atomic Safety and Licensing Board to avoid duplicative reviews in such cases.

The commenter and other companies are currently preparing COL applications under DOE's 2010 program, which is intended to lead to the deployment of new units, particularly Gen II+ units, in a timeframe that is likely to lead to parallel COL, design certification, and ESP

proceedings. In addition, the commenter noted that the Energy Policy Act of 2005 provides incentives for the development of new units, which may affect the applicant's choice of schedule. The commenter noted as an example that in order to qualify for the production tax credit, a company must submit its COL application by the end of 2008. [See IRS Bulletin No. 2006-18 (May 1, 2006), Notice 2006-40] The commenter stated that COL applicants may not be able to wait until design certification proceedings for their selected technology or ESP proceedings for their selected sites are complete. The commenter acknowledged that while the NRC's procedures should not be dictated by these programs and incentives, it is reasonable for the NRC to take steps to ensure that its process is not an impediment to prompt deployment of the most current, passively safe designs. The commenter went on to state that if a design for which a design certification application has been submitted would be subject to duplicative review and litigation in a COL proceeding, attractive new designs like the Economic Simplified Boiling Water Reactor might be at a disadvantage and that similarly, the NRC should take steps to ensure that prompt consideration of site suitability issues is not deterred.

Further, the commenter stated that duplicative review of issues already being addressed in another referenced proceeding would be a costly and inefficient use of the NRC's resources, which are already likely to be challenged by the number of expected applications, and would constitute an undue burden to the applicant. The commenter stated that duplicative reviews could also lead to inconsistent results and loss of standardization. The commenter noted that Part 52 is intended to encourage standardized designs. The commenter stated that this objective would be frustrated for near-term COL applicants who are demonstrating the process and who would be required to obtain plant-specific design reviews in their COL proceedings.

The commenter also noted that avoiding duplicative reviews would be consistent with past NRC practice and case law. The commenter noted that in the Private Fuel Storage case, the NRC staff did not duplicate the review of the cask design issues that were being reviewed for a certificate of compliance. The commenter noted that in addition, case law has long held that Licensing Boards should not accept contentions which are or are about to become the subject of rulemaking. [See *Duke Energy Corp. (Oconee Nuclear Station, Units 1, 2, & 3)*, CLI-99-11, 49 N.R.C. 328, 345 (1999).] The commenter also noted that in *UCS v. AEC*, 499 F.2d 1069 (D.C. Cir. 1974), the DC Circuit upheld the Commission's discretion to exclude issues from consideration in a licensing proceeding when those issues are being considered in a rulemaking proceeding. The commenter stated that as a general matter, the NRC clearly has the discretion to define the scope of its proceedings. [*Bellotti v. NRC*, 725 F.2d 1380, 1381 (DC Cir. 1983).]

The commenter recommended that the NRC should amend 10 CFR§ 52.27(c) and 55.55(c) to exclude from the scope of review and hearing in a COL proceeding those issues that are being resolved in a pending ESP or design certification proceeding referenced in the COL application.

NRC Response: The Commission agrees with the commenter that under existing NRC caselaw, matters which are or about to become the subject of NRC rulemaking, such as a standard design certification, should not be the subject of admitted contentions in a nuclear power plant licensing proceeding. Potomac Electric Power Co. (Douglas Point Nuclear Generating Station, Units 1 and 2), ALAB-218, 8 AEC 79, 85, 89 (1974). However, there is no need for a rulemaking provision in Part 52 to establish the applicability of this principle to combined license proceedings. The caselaw of the NRC applies to all NRC proceedings, including future combined license proceedings referencing an application for a design

certification. Furthermore, this principle also applies in early site permit proceedings, and manufacturing license proceedings, but the commenter did not suggest that parallel provisions be adopted for those matters. Adopting the commenter's proposed changes to §§ 52.27 and 52.55, but not to Subparts A and F of Part 52 could lead to the erroneous conclusion that the principle does not apply in those types of proceedings.

The Commission disagrees with the commenter's proposal for a rulemaking provision that would preclude duplicative reviews and litigation of issues in a combined license proceeding which references an early site permit application. Although the Commission agrees that duplicative review should be avoided, the particular manner in which duplication would be avoided depends upon the circumstances present at the time that the early site permit is referenced by the combined license application. For example, if an early site permit and a combined license application were filed simultaneously (or near simultaneously), the manner in which the Commission may notice and conduct the early site permit and combined license hearings (e.g., a consolidated hearing) may be quite different from the situation where the combined license application referencing the early site permit application is filed at the time of imminent issuance of the referenced early site permit. It would likely prove difficult to develop such rule language (or, as the commenter suggested as an alternative, a policy statement) that would be clearly and understandable to all stakeholders, especially in view of the fact that the Commission has no direct experience with combined license applications referencing early site permit applications. The Commission believes that the provisions in the Part 52 final rulemaking will largely address the concerns of the commenter with respect to duplicative reviews.

For these reasons, the Commission declines to adopt the commenter's proposal and no change to the final has been made in response to the comment.

Comment 013-3: A commenter urged the NRC to avoid reopening issues already resolved as a result of the NRC's design-centered approach or as a result of reviews of Early Site Permit (proposed § 52.27(c)) or Design Certification (proposed § 52.55(c)) applications.

NRC Response: In general, the Commission agrees with the commenter that the issues resolved in a standard design certification rulemaking should not be reopened in subsequent combined license, construction permit, or manufacturing license proceedings which reference the design certification rule.

The Commission also agrees with the implicit suggestion of the commenter that design matters that have been resolved by the NRC in a design centered approach should not ordinarily be "reopened" or otherwise reconsidered as part of each individual combined license application. To facilitate the design-centered approach, the Commission is retaining Appendix N in Part 52, and modify its provisions as well as those of Subpart D of Part 2. These provisions should address the commenter's suggestion for issue finality in the design-centered approach.

The Commission's position on issue resolution and finality with respect to early site permits is set forth in elsewhere as part of the NRC's response to comments on early site permit issue resolution and finality, and the NRC's response to Commission Question 9.

NRC Should Not Require ESP Applicants to Perform Radiation Consequences Analyses

Comment 007-13: Several commenters noted that proposed 10 CFR 52.17(a)(1)(ix) would require an ESP applicant to evaluate postulated fission product releases consistent with 10 CFR § 50.34 using containment leak rates and fission product cleanup systems. The commenters stated that modification of proposed § 52.17(a)(1) is needed to reflect the ability to seek and obtain an ESP without specifying the design to be built and without providing specific design information. The commenters stated that a lesson learned from the existing ESP proceedings is that final radiation consequence analyses should not be a requirement for ESP. Instead, the commenters suggested that Part 52 should allow such an analysis to be performed and provided for NRC review by ESP applicants if the requisite design-specific information is known. If not, and similar to the approach for addressing EP and security plans, the ESP applicant should be required to demonstrate that Part 100 requirements can be met by providing sample radiation consequence analyses based site characteristic atmospheric dispersion factors (X/Q).

The commenters stated that while they generally agree with the NRC staff on the acceptability of the plant parameter envelope (PPE) approach for ESP applicants who have not selected a specific design for their site, they do not believe that proposed § 52.17(a)(1) adequately reflects this approach. The commenters noted that under the PPE approach, an ESP applicant does not seek approval of the site for specific facilities; rather, bounding design information is used as a surrogate for actual facility information to support the ESP review and approval is sought for a reactor or reactors that fall within the PPE.

The commenters stated that, depending on the approach selected by an ESP applicant, the radiological consequence analyses that can meaningfully be performed and provided for NRC review are different. The commenters stated that ESP applications based on a specific design may be able to present complete radiological consequence analyses that demonstrate that Part 100 radiological dose criteria are met for the proposed site/design combination. Section 52.17(a)(1) should not require complete radiological consequence analyses even for applicants that seek approval of the site for a specific facility because the specified facility may not be a certified design. If the ESP application is based on a specific, non-certified design, the design-specific information necessary for complete radiological consequence analyses may not yet be available, or may be subject to change. NRC review and approval of accident sequences, release histories and related design-specific information would be expected in a design certification or combined license proceeding, not in an ESP proceeding. However, the commenters went on to say that if the ESP applicant has not selected a specific design, complete radiological consequence analyses, which require knowledge of design-specific accident sequences, release histories, etc., cannot be meaningfully accomplished. Instead, the commenters suggested that the focus for these ESP applicants should be on the site-related aspects of radiological consequence analyses, i.e., determination of site atmospheric dispersion characteristics.

The commenters stated that the determination that radiological dose consequence criteria are met can only be made when both the site and design are known. The commenters noted that the existing ESP applicants are using the PPE approach and have not specified a particular design as the basis for their applications. Their radiological consequence analyses are based

on bounding analyses; design-specific analyses will be required to be submitted in any combined license application referencing the ESPs.

The commenters suggested that for an ESP application, the acceptability of the site with respect to radiological dose consequence criteria should be dependent on the site characteristic X/Q, including any assumptions related to the structures, systems and components (SSCs) that bear significantly on the calculation of X/Q such as elevated release point and building locations associated with assumed wake effects. The commenters noted that at the COL stage, the site X/Q will need to be combined with the release history information provided in a design certification, or approved during the COL review of an uncertified design, to determine whether dose requirements are met for the specific plant.

The commenters stated that the NRC provides no explanation in the Supplementary Information as to why it would require an ESP applicant to evaluate postulated fission product releases using containment leak rates and fission product cleanup systems. The commenters stated that the provision is inappropriate and, as discussed above, is potentially impossible to satisfy for an ESP applicant using the PPE approach.

NRC Response: The NRC agrees that § 52.17(a)(1) should reflect the option for ESP applicants to use postulated design parameters in lieu of actual design information but notes that this allowance was provided for in the proposed rule. Specifically, § 52.17(a)(1)(i) states that the application must contain the specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used [emphasis added]. The NRC does not agree, however, that changes are needed to clarify the nature of radiological consequence analyses that are required of ESP applicants. This issue has been discussed with NEI in public meetings and in letters from the NRC dated February 5 and June 20, 2003 (ADAMS Accession Nos. ML030210341 and ML031150617), on the resolution of Early Site Permit Topic 7 (ESP-7), which involved guidance for satisfying 10 CFR 52.17(a)(1) requirements. The NRC staff also addressed the issue in SECY-03-0105, "Early Site Permit Application Readiness," dated June 24, 2003, and in NRC's August 4, 2003 letter to NEI providing the NRC's responses to NEI's comments on draft Review Standard (RS)-002, "Processing Applications for Early Site Permits," Sections 15 and 17.1.1 (ADAMS Accession No. ML031920465). During all of these discussions, the NRC has consistently maintained that dose consequence evaluation factors must be considered in an ESP application as required by § 52.17(a)(1).

The NRC's regulations in 10 CFR Part 100, "Reactor Site Criteria," present a framework that guides the NRC in its evaluation of the suitability of proposed sites for stationary power and test reactors. The regulations recognize the importance of accident considerations in reactor siting and key elements are the determination of the size of the exclusion area considering postulated accidents with a large fission product release within containment and the evaluation of the radiological consequences in terms of doses.

Accident considerations historically have been of key importance in reactor siting. Major developments in risk assessment, such as the issuance of the Reactor Safety Study (WASH-1400), and NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," as well as the occurrence of the Three Mile Island accident in 1979 and the accident at Unit 4 of the Chernobyl reactor in the Soviet Union in 1986, have heightened awareness, knowledge, and concerns in this area. Siting factors and criteria are important in assuring that

radiological doses from normal operation and postulated accidents will be acceptably low. In 1996, the NRC amended its regulations to update the criteria used in decisions regarding power reactor siting (61 FR 65176; December 11, 1996). In that rulemaking, the NRC modified source terms and dose calculation requirements that apply primarily to plant design and relocated them to 10 CFR Part 50. Conforming changes were made to 10 CFR Part 52 to reflect these changes.

As articulated in Regulatory Guide 4.7, "General Site Suitability Criteria for Nuclear Power Stations," which was revised in conjunction with the 1996 rule, both the exclusion area boundary described by 10 CFR 52.17(a)(1)(ix)(A) and the low population zone described by 10 CFR 52.17(a)(1)(ix)(B) (both of which are defined in 10 CFR 50.2) depend on site characteristics and aspects of the plant design. In effect, certain elements of siting and design have been inextricably linked and remain so.

Based on this regulatory history, the NRC continues to believe that dose consequence evaluation factors must be considered by ESP applicants as required by 10 CFR 52.17(a)(1). Requirements in 10 CFR Part 100, which are defined as the siting requirements for 10 CFR Part 52 applicants, must be met for the NRC to approve "a site for one or more nuclear power facilities separate from the filing of an application for a...combined license for such a facility" (§ 52.12), and therefore must be addressed at the ESP stage. While the meteorology is solely dependent on the site, the site atmospheric dispersion factors have a dependency on the design parameters (e.g., height of building cross-section for evaluation of the building wake effects) and the footprint of the plant (e.g., for determination of the distance of the release location to the exclusion area boundary). Therefore, the site atmospheric dispersion factor alone cannot be used to meet the criteria for radiological dose consequences of postulated accidents as required by Section 52.17(a)(1) because both site characteristics and design information are necessary in order to perform the required assessment. If an ESP applicant pursues the plant parameter envelope approach, the staff expects the application information to include the bounding reactor accident source terms, in addition to site atmospheric dispersion factor values, so that the staff can evaluate the acceptability of the site under the radiological consequence evaluation factors identified in 10 CFR 52.17(a)(1)(ix).

At the COL stage, an applicant referencing an ESP that used a plant parameter envelope approach would be required, in accordance with § 52.79(b), to provide information sufficient to demonstrate that the design of the facility falls within the site characteristics and bounding design parameters specified in the early site permit. Therefore, if the COL applicant can demonstrate that the characteristics of its actual facility design are bounded by the PPE values it postulated at the ESP stage, then no further analysis is necessary regarding compliance with Part 100.

The commenters suggested that the ESP approach for addressing compliance with Part 100 requirements should be similar to that used in the current rule to address emergency planning. Section 52.17(a)(1) requires ESP applicants to "identify physical characteristics of the proposed site ... that could pose a significant impediment to the development of emergency plans." The commenters stated that in that way, the rule recognizes that while emergency planning is an important consideration in determining site suitability, the ESP applicant may not be able to demonstrate compliance with Part 50, Appendix E, requirements at the ESP stage. Rather, the commenters asserted that the only requirement for ESP is to identify significant impediments to development of emergency plans, and if there are any, measures to mitigate or eliminate them.

The commenters noted that the proposed rule uses a similar approach to address adequate security plans. Proposed § 52.17(a)(1)(xi) requires ESP applicants to demonstrate that “site characteristics are such that adequate security plans and measures can be developed.”

The commenters stated that, like EP and security, radiation dose consequence criteria cannot be shown to be met at the ESP stage if the applicant has not selected a design and/or does not have the necessary design information available, such as information on systems, structures, components and source terms. The commenters stated that “such an ESP applicant could, however, demonstrate that radiation dose consequence criteria can be met by providing a sample analyses based on a typical plant design and site characteristic X/Q.” The commenters stated that this is similar to the approach used by the NRC staff and the first three applicants for ESP. The commenters noted that a COL applicant referencing such an ESP would be required to perform specific radiation dose consequence analyses for the specific design selected, and these analyses would be subject to NRC review.

The commenters suggested that if an ESP applicant has selected a design and has the necessary design information, the applicant may provide design-specific radiation dose consequence analyses, using the site characteristic X/Q. The commenters stated that once these analyses are approved in the ESP, compliance with Part 100 dose consequence criteria would be considered resolved for future applicants referencing the ESP, consistent with Section 52.39(a)(2), and these analyses would not be subject to further NRC review.

NRC Response: The NRC agrees that § 52.17(a)(1) should reflect the option for ESP applicants to use postulated design parameters in lieu of actual design information but notes that this allowance was provided for in the proposed rule. Specifically, § 52.17(a)(1)(i) states that the application must contain the specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used [emphasis added]. The NRC does not agree, however, that changes are needed to clarify the nature of radiological consequence analyses that are required of ESP applicants. This issue has been discussed with NEI in public meetings and in letters from the NRC dated February 5 and June 20, 2003 (ADAMS Accession Nos. ML030210341 and ML031150617), on the resolution of Early Site Permit Topic 7 (ESP-7), which involved guidance for satisfying 10 CFR 52.17(a)(1) requirements. The NRC staff also addressed the issue in SECY-03-0105, “Early Site Permit Application Readiness,” dated June 24, 2003, and in NRC’s August 4, 2003 letter to NEI providing the NRC’s responses to NEI’s comments on draft Review Standard (RS)-002, “Processing Applications for Early Site Permits,” Sections 15 and 17.1.1 (ADAMS Accession No. ML031920465). During all of these discussions, the NRC has consistently maintained that dose consequence evaluation factors must be considered in an ESP application as required by § 52.17(a)(1).

The NRC’s regulations in 10 CFR Part 100, “Reactor Site Criteria,” present a framework that guides the NRC in its evaluation of the suitability of proposed sites for stationary power and test reactors. The regulations recognize the importance of accident considerations in reactor siting and key elements are the determination of the size of the exclusion area considering postulated accidents with a large fission product release within containment and the evaluation of the radiological consequences in terms of doses.

Accident considerations historically have been of key importance in reactor siting. Major developments in risk assessment, such as the issuance of the Reactor Safety Study (WASH-

1400), and NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," as well as the occurrence of the Three Mile Island accident in 1979 and the accident at Unit 4 of the Chernobyl reactor in the Soviet Union in 1986, have heightened awareness, knowledge, and concerns in this area. Siting factors and criteria are important in assuring that radiological doses from normal operation and postulated accidents will be acceptably low. In 1996, the NRC amended its regulations to update the criteria used in decisions regarding power reactor siting (61 FR 65176; December 11, 1996). In that rulemaking, the NRC modified source terms and dose calculation requirements that apply primarily to plant design and relocated them to 10 CFR Part 50. Conforming changes were made to 10 CFR Part 52 to reflect these changes.

As articulated in Regulatory Guide 4.7, "General Site Suitability Criteria for Nuclear Power Stations," which was revised in conjunction with the 1996 rule, both the exclusion area boundary described by 10 CFR 52.17(a)(1)(ix)(A) and the low population zone described by 10 CFR 52.17(a)(1)(ix)(B) (both of which are defined in 10 CFR 50.2) depend on site characteristics and aspects of the plant design. In effect, certain elements of siting and design have been inextricably linked and remain so.

Based on this regulatory history, the NRC continues to believe that dose consequence evaluation factors must be considered by ESP applicants as required by 10 CFR 52.17(a)(1). Requirements in 10 CFR Part 100, which are defined as the siting requirements for 10 CFR Part 52 applicants, must be met for the NRC to approve "a site for one or more nuclear power facilities separate from the filing of an application for a...combined license for such a facility" (§ 52.12), and therefore must be addressed at the ESP stage. While the meteorology is solely dependent on the site, the site atmospheric dispersion factors have a dependency on the design parameters (e.g., height of building cross-section for evaluation of the building wake effects) and the footprint of the plant (e.g., for determination of the distance of the release location to the exclusion area boundary). Therefore, the site atmospheric dispersion factor alone cannot be used to meet the criteria for radiological dose consequences of postulated accidents as required by Section 52.17(a)(1) because both site characteristics and design information are necessary in order to perform the required assessment. If an ESP applicant pursues the plant parameter envelope approach, the staff expects the application information to include the bounding reactor accident source terms, in addition to site atmospheric dispersion factor values, so that the staff can evaluate the acceptability of the site under the radiological consequence evaluation factors identified in 10 CFR 52.17(a)(1)(ix).

At the COL stage, an applicant referencing an ESP that used a plant parameter envelope approach would be required, in accordance with § 52.79(b), to provide information sufficient to demonstrate that the design of the facility falls within the site characteristics and bounding design parameters specified in the early site permit. Therefore, if the COL applicant can demonstrate that the characteristics of its actual facility design are bounded by the PPE values it postulated at the ESP stage, then no further analysis is necessary regarding compliance with Part 100.

Comment 008-2: A commenter brought up the topic of combined permits and licenses but was not aware that any have been requested yet. The commenter stated that the site permit material includes design concepts, a plant parameter envelope, and pointed out that it is not apparent that the site approval applications were for a specific design like they were in the past.

The commenter asked when in the process the NRC plans to evaluate the specific design that a party wants to build so that the NRC can evaluate how the design copes with the environmental extremes, how the public is going to be protected from accidents, how the design can impact the environment, and what can be done to make the impact even smaller. The commenter asked if the NRC should instead require applicants to show the actual designs that they want to build on the sites they want approved instead of a concept. The commenter stated that, locally, industry cannot obtain a building permit until the architect's plans have been approved. Similarly, the commenter suggested that the NRC should not approve construction and operation until the actual design for the place on the site. The commenter also noted that it is not clear what value the envelope has in the rule, and questioned whether it can work years in advance of the actual decision to build something, and requested that it be defined to avoid "bait and switch."

NRC Response: The commenter is correct in that an early site permit applicant need not specify a particular design in its application. The regulations allow applicants to specify a range of designs that are under consideration. Such a range of designs can be described by using a "plant parameter envelope." When the early site permit is referenced in a combined license application, however, the combined license applicant must specify the specific design it intends to build at the site. The NRC only approves construction and operation of the facility when the combined license is issued, so, contrary to the commenters assertion, the NRC does not approve construction and operation until the actual design of the facility is known.

New Requirement for ESP Applicants to Provide ITAAC

Comment 007-16: Several commenters noted that proposed 10 CFR 52.17(b)(3) would require ESP applicants to provide inspections, tests, analyses, and acceptance criteria (ITAAC) on emergency planning (EP) for both major features or complete programs. The commenters also noted that proposed § 52.24(a)(5) would require a Commission finding that the ESP proposed ITAAC, "including any on emergency planning," are necessary and sufficient to make a reasonable assurance finding, and that the Supplementary Information for the proposed rule (71 FR 12789) explains the purpose of these proposed provisions. The commenters stated that an ESP applicant should not be required to propose EP ITAAC for major features of an EP plan.

The commenters noted that this discussion is inconsistent with proposed § 52.17(b)(3) in that it focuses solely on the need for EP ITAAC when the ESP application includes complete and integrated emergency plans. The commenters stated that the Supplementary Information does not identify the need for EP ITAAC when the ESP application includes only EP "major features." The commenters believe the Supplementary Information is correct and that EP ITAAC should not be required for the "major features" option. The commenters stated that the NRC does not need to make a reasonable assurance finding with respect to the description of "major features" of an EP plan submitted at the ESP stage. Instead, the commenters noted that under 10 CFR 52.18, the NRC is only required to determine that the major features are "acceptable." The commenters concluded that, using the staff's rationale, EP ITAAC are not necessary. The commenters noted that the first three ESPs each reflect use of the "major features" option and are progressing toward NRC approval without ITAAC on EP major features.

The commenters also stated that it may not be possible to develop ITAAC for EP major features at the ESP stage because, by definition, information on EP major features will not include details of the complete EP program. The commenters suggested that because in some cases it might be necessary to have those EP program details in order to develop appropriate EP ITAAC, development of EP ITAAC should be deferred to the COL stage when detailed EP program information will be available.

The commenters noted that in preliminary discussions between NRC and the commenters on this topic, it has been acknowledged that the existing language in Part 52 does not preclude any ESP applicant from proposing EP ITAAC. Given the possibility that EP ITAAC may in the future be determined to be practical and useful for ESP applicants using the “major features” option, the commenters would not object to adding a permissive provision to the end of Section 52.17(b)(3).

Finally, the commenters recommend that Section 52.24(a)(5) be modified to reflect that EP ITAAC are the only type of ITAAC envisioned for ESPs.

NRC Response: NRC agrees in part with the commenter. Specifically, the staff agrees with NEI that the ESP applicant should not be required to propose EP ITAAC for major features of an EP plan, and that 10 CFR 52.17(b)(3) should be modified to reflect the commenter’s proposed revision, including the permissive provision. The staff does not agree that the language “after [insert date of final rule]” should be added, as this is considered unnecessary because any ESP application with complete and integrated emergency plans must include some EP ITAAC, regardless of whether they are submitted prior to or after the effective date of this rulemaking. While the current rules do not require EP ITAAC for complete and integrate emergency plans in an ESP application, a reasonable assurance determination can not be made without them. Further, the current rules do not preclude submission of ESP EP ITAAC for complete and integrated emergency plans. Thus, the effective date of the rulemaking requirement for ESP EP ITAAC for complete and integrated plans is inconsequential, as it relates to the NRC (and DHS) reasonable assurance determination. Further, the staff does not agree that 10 CFR 52.24(a)(5) should be modified to reflect that EP ITAAC are the only type of ITAAC envisioned for ESPs. The staff believes that the existing language provides additional flexibility for ESP applicants, in that they would be allowed to propose ITAAC for areas other than emergency planning, if they so desire.

New Requirement for ESP Applicants to Address Construction Impacts on Existing Plants

Comment 007-20: Several commenters noted that proposed 10 CFR 52.17(a)(1)(x) would require ESP applicants to address impacts on operating units of constructing new units on existing sites. The commenters stated that this provision in the proposed rule is contrary to the industry-NRC understanding on this matter, as documented in correspondence in 2003 regarding ESP Topic ESP-19 (see NEI Letter dated May 14, 2003, and NRC Letter dated August 11, 2003). The commenters noted that, as discussed by the NRC at the workshop on March 14, 2006 (Tr. 78-79), NRC apparently did not consider ESP-19 when it prepared the proposed rule, and it does not know why it changed its position. The commenters believe that the requirement proposed in § 52.17(a)(1)(x) is both unnecessary and potentially impossible for an ESP applicant to implement, and suggested that therefore, this provision should be deleted.

The commenters stated that, consistent with the resolution of ESP-19, the COL applicant (and not the ESP applicant) should have the obligation to identify the impacts of construction on existing operating plants. The commenters stated that the COL applicant is in the best position to provide such information, since it will have final information regarding the design and construction plans. In contrast, the commenters stated that the ESP applicant will not have final design information or construction plans. Therefore, the commenters stated that it will be difficult, if not impossible, for an ESP applicant to provide the information specified in the proposed rule. The commenters also stated that in any event, the issue does not relate to site suitability.

The commenters noted that proposed 10 CFR 52.79(a)(31) includes a requirement for a COL applicant to include such information in the COL application on construction impacts, and that provision reflects the current requirements in 10 CFR 50.34(a)(11). The commenters state that this approach also is consistent with the staff's comments in its December 27, 2005, response to the Commission's SRM. Therefore, the commenters concluded that there is no need to impose this requirement on ESP applicants.

Comment 012-9: A commenter stated that they are concerned that the proposed rule would unnecessarily expand the safety review in an ESP proceeding. The commenter stated that proposed § 52.17(a)(1)(x) would expand the safety review in an ESP proceeding to include an evaluation of the potential hazards to operating units from construction activities, as well as a description of the managerial and administrative controls to be used to assure that the limiting conditions of operation for existing units will not be exceeded. The commenter asserted that this proposal would make the ESP process more burdensome without any commensurate safety benefit.

The commenter noted that under the current regulations, the requirement to evaluate the potential hazards to operating units from construction activities applies only at the COL stage. The commenter stated that the current requirement in 10 CFR 50.34(a)(11) is not one of the requirements incorporated into 10 CFR § 52.17(a)(1) and therefore does not apply to an ESP application. The commenter noted that in a letter dated August 11, 2003 to NEI, the NRC stated, "The NRC staff agrees that the requirements of 10 CFR § 50.34(a)(1) are not applicable to an ESP application."

The commenter stated that the NRC now proposes to make this evaluation a new requirement for ESP applicants "so that all applicable issues are included in the NRC's review of site suitability. . ." [See 71 FR 12790] The commenter asserted that the proposed evaluation and requirement to establish managerial and administrative controls go far beyond any review that is needed to determine the suitability of the site. The commenter suggested that at most, any consideration of this issue should be limited to whether the presence of the existing units would preclude the construction of additional units. The commenter stated that because construction has been performed without problem at many operating units, the only question should be whether there are any unique characteristics of site or existing units that would pose any insurmountable impediment to constructing new units.

The commenter stated that as a practical matter, information may not exist at the ESP stage to perform a specific evaluation of the potential hazards from construction, because the design and footprint of the new units may not be known. The commenter further stated that the

evaluation may be premature, because construction may not occur for many years. The commenter noted that an ESP remains valid for 20 years and may be renewed.

The commenter stated that a safety review is not needed for those preconstruction activities that an ESP holder may perform pursuant to 10 CFR 52.25(a). The commenter noted that such a review is not required in order to authorize these preconstruction activities under 10 CFR 50.10(e), and therefore should not be required for an ESP. The commenter stated that the NRC staff has acknowledged that an “ESP does not authorize construction activities that could pose safety/security issue[s] to existing operating units onsite.” [See Attachment to Memorandum from EDO to Commissioners, “Response to Staff Requirements Memorandum” (Dec. 27, 2005)] The commenter added that moreover, administrative controls already exist at any site on which reactors are already operating. The commenter stated that a licensee for an operating unit has the authority to determine all activities in the exclusion area. [See 10 CFR 100.3.] The commenter noted that in addition, the licensee is required by 10 CFR 50.59 to evaluate changes to its facility. The commenter stated that proposed construction activities would also be evaluated by the licensee for operating units under its site access and security programs. The commenter asserted that there is, therefore, simply no need for these proposed new requirements.

NRC Response: The NRC agrees that proposed § 52.17(a)(1)(x) was contrary to the industry-NRC understanding on this matter, as documented in correspondence in 2003 regarding ESP Topic ESP-19 (see NEI Letter dated May 14, 2003 (ML031920246), and NRC Letter dated August 11, 2003 (ML031490478)) and that the COL applicant is in the best position to provide such information, since it will have final information regarding the design and construction plans. The NRC is considering whether to include a condition in early site permits that would require the permit holder to notify the operating plant licensee prior to conducting any activities authorized under § 52.25. These controls should be sufficient to evaluate construction activities at a site with an existing operating unit and the NRC has deleted this provision from subpart A in the final rule. COL applicants will, however, continue to be required to meet this provision under § 52.79(a)(31).

Delayed response by an ESP holder to information requests

Comment 007-31: Several commenters noted that proposed § 52.39(e) would allow the NRC to request information from an ESP holder if the staff first evaluates the burden to be imposed “in view of the potential safety significance of the issue to be addressed in the requested information,” and if the evaluation conforms to 10 CFR 50.54(f). The commenters also noted that the proposed new provision also states that such an evaluation is not necessary if the request seeks to verify compliance with the current licensing basis of the ESP. The commenters stated that the proposed rule should be modified to allow the ESP holder to defer a response to NRC questions until the COL proceeding or until the ESP holder submits a request for renewal of the ESP. The commenters stated that such an allowance is appropriate for several reasons: (1) an ESP holder will not necessarily maintain (and should not be required to maintain) a technical staff to respond to information requests from the NRC, and therefore, an ESP holder may not be able to submit an appropriate response until the COL proceeding application or until the ESP holder submits a request for renewal of the ESP; (2) an ESP holder is not allowed to perform any safety-related construction activities, therefore, there will be no adverse impact upon safety if the ESP holder is allowed to defer a response to an NRC request

for information; and (3) an ESP holder may never submit a COL application. The commenter concluded that in such an event, the NRC's request for information would be moot.

NRC Response: The NRC does not agree with the commenters that the proposed rule should be modified to allow the ESP holder to defer a response to NRC questions until the COL proceeding or until the ESP holder submits a request for renewal of the ESP. The commenters claimed that an ESP holder will not necessarily maintain (and should not be required to maintain) a technical staff to respond to information requests from the NRC. An ESP holder, like any other licensee, is required under § 50.71(a) to "maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations, and orders of the Commission in effectuating the purposes of the Act, including Section 105 of the Act, and the Energy Reorganization Act of 1974, as amended." Section 50.71(c) requires that "records that are required by the regulations in this part or Part 52 of this chapter, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification." Therefore, it is the ESP holder's responsibility, as it is every licensee's responsibility, to have staff to maintain records and respond to any inquiries from the NRC in a timely fashion.

New Requirements for an ESP Applicant to Evaluate its Application Against the Standard Review Plan (SRP)

Comment 007-39: Several commenters noted that proposed § 52.17(a)(1)(xiii) would require an ESP application to include an evaluation of the site against applicable sections of the Standard Review Plan (SRP) revision that was in effect 6 months prior to the docket date of the application. The commenters noted that the NRC issued RS-002, Processing Applications for Early Site Permits, as guidance for ESP application review. The commenters recommended that the final Part 52 rule should have flexibility to allow an ESP application to provide an evaluation against RS-002 or other NRC applicable guidance documents, in lieu of an evaluation against the SRP.

NRC Response: The NRC does not agree with the commenters' recommendation that the final Part 52 rule should have flexibility to allow an ESP application to provide an evaluation against RS-002 or other NRC applicable guidance documents, in lieu of an evaluation against the SRP. The NRC plans to have the current SRP revision finalized by March 31, 2007. At that time, the majority of the contents of RS-002 will be replaced with information indicating the SRP sections that are applicable to NRC review of an ESP.

Deletion of Provision that an ESP is a "Partial Construction Permit"

Comment 007-44: Several commenters noted that the proposed rule would delete the statement in 10 CFR 52.21 that an ESP is a "partial construction permit." The commenters stated that the Supplementary Information for the proposed rule does not explain the purpose, intent, or effect of deleting this provision in the current rule. The commenters also noted that, despite the deletion in the rule language, the NRC continues to refer to an ESP as a partial construction permit at various places throughout the NOPR (see 71 FR 12790, 12791, 12809, 12812, and 12815). The commenters stated that therefore, the NOPR is not internally consistent, and it is unclear whether the Commission intends for the deletion to have any substantive effect.

The commenters believe that the proposed change would remove some clarity afforded by the current rule. The commenters stated that this proposed deletion could result in certain benefits being removed from the ESP, since it would no longer have the status of a partial construction permit. Furthermore, the commenters stated that the existing provision is useful, and there is no reason why an ESP should not continue to be referred to as a partial construction permit.

NRC Response: The NRC does not agree with the commenter that it is necessary to re-instate the referenced provision in current § 52.21. That provision states that, "An early site permit is a partial construction permit and is therefore subject to all procedural requirements in 10 CFR Part 2 which are applicable to construction permits." Although the NRC continues to view an ESP as a partial construction permit, the NRC does not believe it is necessary to state so in the rule. One of the main goals of this rulemaking is to make conforming changes throughout 10 CFR so that all of the related regulations contain specific requirements for Part 52 licenses, certifications, and approvals. In doing so, the NRC has removed the need to couch Part 52 requirements in terms of their relation to requirements for construction permits and operating licenses. For example, Part 2 has been revised to explicitly address ESPs, so there is no need to state that an ESP is a partial construction permit subject to requirements applicable to construction permits. However, because the NRC did not intend any substantive effect by its removal of the language referring to ESPs as a partial construction permit, other than to indicate that the entire body of NRC regulations now contain requirements specific to ESPs, it is revising the definition of an ESP in § 52.1 to include a statement that an ESP is a partial construction permit, in deference to the commenters. The NRC believes that § 52.1 is a more appropriate location for such a statement. Placing the statement in the ESP definition is consistent with the NRC definition of a COL, wherein that definition states that a COL is a combined construction permit and operating license with conditions.

The Proposed Rule Would Allow the NRC Arbitrarily to Withhold the Issuance of an ESP

Comment 007-45: Several commenters noted that proposed § 52.24(a) states that the Commission *may* issue an ESP if it makes the requisite findings. In contrast, the commenters noted that the current rule states that the Commission *shall* issue the ESP if it makes the requisite findings. The commenters stated that the Supplementary Information for the proposed rule provides no explanation or justification for this proposed amendment. The commenters stated that the proposed provision would enable the NRC arbitrarily to withhold issuance of an ESP, even though the ESP application has satisfied all applicable requirements. The commenters stated that the NRC should be required to issue the ESP in such cases.

NRC Response: The Commission disagrees with the commenter's legal analysis, to the extent that it suggests that the Commission's use of the term, "may," affords the Commission to legal authority to act arbitrarily and capriciously in withholding an ESP. No administrative agency has the authority to act in derogation of the Administrative Procedure Act and applicable federal caselaw - much less the authority to adopt a regulation which effectively grants itself dispensation from compliance with applicable law. The Commission regards the use of the term, "may," as consistent with and in furtherance of the AEA's direction that licenses shall not be issued if the Commission believes that issuance of the license would be "inimical to the common defense and security or to the health and safety of the public." AEA, Section 103.e. as the Commission has stated on other occasions, compliance with the Commission's regulations are merely presumptive of adequate protection to public health and safety and common

defense and security. See 53 FR 41178, 41179-80 (October 20, 1988); 50 FR 20603, 20609 (June 6, 1988).³ There may be circumstances where an safety issue has been identified but has yet to be addressed through rulemaking. In such cases, the Commission may, under the authority of Section 103.e., lawfully decline to issue the license, or issue the license with conditions addressing the safety issue, despite the applicant having demonstrated compliance with all relevant Commission regulations. The use of the term, “may,” reflects the Commission’s authority in this regard, and avoids the need for the Commission in this circumstance to issue itself a dispensation from compliance with its own regulation.

Moreover, the commenter does not address other Commission regulations governing issuance of reactor licenses that uses the term “may,” e.g., § 54.29 (renewed operating licenses under Part 54; Part 52, Appendix M, paragraph 10 (manufacturing licenses for nuclear power plants), which would appear to suffer the same “defect” complained of by the commenter. The commenter also does not appear to recognize that the Commission proposes to standardize on the term, “may,” throughout Part 52, see § 52.54(a)(standard design certification); and § 52.97(a)(1)(combined license). The Commission does not regard any of these regulations as authorizing arbitrary and capricious action by the Commission in the issuance of licenses.

In sum, the use of the term, “may” affords the Commission the authority to deny issuance of a license despite a finding of compliance with the Commission’s regulations, if the Commission has identified either a public health and safety or common defense and security issue not addressed by its regulations. Accordingly, the Commission declines to adopt the commenter’s suggested change to § 52.24(a), and no change to any part of the final rule has been made as the result of the comment.

The Proposed Rule Would Allow Litigation of Changes to ESP Emergency Planning Information That Are Not Significant to Safety

Comments 007-46: Several commenters noted that proposed 10 CFR 52.39(c)(1)(iv) would allow litigation in a COL proceeding referencing an ESP contentions on “new or additional information” provided in the COL application “which materially affects the Commission’s earlier determination on emergency preparedness” in the ESP proceeding, or “is needed to correct inaccuracies in the emergency preparedness information approved in the early site permit.” The commenters stated that this proposed provision identifies a different standard for emergency planning contentions than that in 10 CFR 50.54(q). The commenters noted that § 50.54(q) allows a licensee to make changes in an NRC-approved emergency plan, without prior NRC approval, if the change does not decrease the effectiveness of the plan and the plan as changed continues to meet the requirements in Appendix E to Part 50. The commenters stated that this standard ensures adequate protection of safety, and has been accepted and used by the industry and NRC for years. The commenters stated that this same standard should be applied to changes in emergency plans approved by the NRC in the ESP proceeding, and that the NRC has not explained the basis for or justified the higher standard in the proposed rule.

³NRC staff actions have been consistent with this principle, see, e.g., *FirstEnergy Nuclear Operating Company* (Davis-Besse Nuclear Power Station, Unit 1), Directors Decision DD-04-1, 59 NRC 215, 221 (2004).

The commenters stated that proposed § 52.39(c)(1)(iv) is objectionable because it is inconsistent with proposed § 52.39(a)(2). The commenters noted that § 52.39(a)(2) states that, “if the early site permit approved an emergency plan (or major features thereof) that are in use by a licensee of a nuclear power plant, the Commission shall treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee’s emergency plans in compliance with § 50.54(q) of this chapter occurring after issuance of the early site permit.” The commenters concluded that therefore, proposed § 52.39(c)(1)(iv) would appear to allow intervenors to raise contentions on material changes that have “finality” under proposed § 52.39(a)(2), which is inconsistent with the concept of finality.

The commenters contended that, even more fundamentally, there is no reason for the NRC to distinguish between approved emergency plans for ESPs for existing reactor sites and approved emergency plans for ESPs on greenfield sites. The commenters stated that as long as the emergency planning information has been approved by the NRC in the ESP proceeding, it should be afforded the same protection whether or not the emergency plan is the same as that being used by an existing plant. The commenters concluded that therefore, all changes to approved emergency planning information should be judged under the standards in § 50.54(q), not just those changes related to sites with an existing nuclear plant.

The commenters also stated that the “materiality” standard in proposed § 52.39(c)(1)(iv) could allow litigation of changes that are not significant to safety. The commenters asserted that, in this regard, the NRC has typically defined “material” as information that has the ability to influence the agency in the conduct of its regulatory responsibilities [See Virginia Elec. and Power Co. (North Anna Power Station, Units 1 and 2), CLI-76-22, 4 NRC 480 (1976) North Anna, CLI-76-22, 4 NRC at 486 and at 491.] The commenters stated that under this definition, a change in emergency planning information may be material, but may not represent a decrease in safety, and that if a change does not adversely affect safety, it should not be subject to NRC approval or hearings.

The commenters suggested that in this regard, it is possible that the proposed rule is defining the term “material” in a manner that is different from the NRC’s traditional definition. The commenters noted that the Supplemental Information for the proposed rule (71 FR 12795) includes the discussion regarding material changes in emergency planning.

NRC Response: The NRC agrees with the commenter in part and has made changes to § 52.39 in the final rule to address this issue. Specifically, the NRC revised § 52.39(a)(2) to add a provision that would provide a COL applicant referencing an ESP that had approved emergency plans that were not in use by a licensee of a nuclear power plant with finality for changes that are equivalent to those that could be made under § 50.54(q) without prior NRC approval had the emergency plan been in use by a licensee. The NRC agrees that this standard ensures adequate protection of safety, and has been accepted and used by the industry and NRC and that it is appropriate to apply this same standard to changes in emergency plans approved by the NRC in the ESP proceeding.

The NRC has also revised § 52.39(c)(iv) as suggested by the commenters to state that contentions may be litigated on matters related to new or additional information provided in the application that substantially alters the bases for a previous NRC conclusion and constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to

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

Inconsistent Treatment of ESPs

Comment 007-65: Several commenters noted that Proposed § 52.39(d) states that a “variance will not be issued once the construction permit, operating license, or combined license is issued.” The commenters stated that in contrast, proposed § 52.27(b)(2) indicates the ESP continues to be valid “in any hearing held under 10 CFR 52.103 before operation begins under a combined license which references the early site permit.” The commenters stated that proposed § 52.39 appears to be based on the presumption that the ESP will be subsumed into the construction permit (CP) or COL. The commenters stated that such a presumption is inconsistent with the proposed § 52.27. The commenters stated that if the ESP remains valid, then NRC regulations should contain a provision that allows for a request for a variance. The commenters went on to state that if the ESP is subsumed into the CP or COL, then no variance is necessary, but the ESP should not be valid during § 52.103 hearings.

The commenters recommended that Part 52 be revised so that an ESP is subsumed within a CP or COL once the latter is issued. The commenters stated that therefore, any terms or conditions (including ITAAC) in the ESP that cannot be resolved during the CP or COL proceeding would need to be included as terms and conditions in the CP or COL. The commenters continued that in addition, Part 52 should allow for cases in which an ESP has a broader scope than the CP or COL. The commenters gave as an example that if the ESP applies to two units but the CP or COL only applies to one unit, the ESP should remain in effect for the balance of the units not encompassed within the CP or COL.

NRC Response: The NRC agrees with the commenters that the language in §§ 52.27(b) and 52.39(d) is inconsistent. It is the NRC’s intention that the ESP be subsumed into the CP or COL once the CP or COL is issued. The NRC agrees that proposed § 52.27(b)(2) should be deleted and it has done so in the final rule. The NRC also agrees with the commenters’ suggestion that a new § 52.27(d) should be added in the final rule to clarify that, upon issuance of an application for a CP or COL that references an ESP, the ESP is no longer effective with respect to that CP or COL. However, the NRC believes it provides greater clarity to say that, upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license. The NRC does not agree that a statement needs to be included in the new § 52.27(d) that states that any terms or conditions in the ESP that could not be satisfied by the time of issuance of the CP or COL shall become terms or conditions of the CP or COL. This is because this statement is being added to § 52.24(b) in the final rule. The NRC believes it is more appropriate to address this issue in the “issuance” section of Subpart A rather than in the “duration” section of Subpart A.

Beneficial Changes Proposed for Part 52

Comment 007-75: Several commenters stated that the industry considers the changes in the NOPR in § 52.17(a)(1)(i), regarding the addition of the phrase, “or range of possible facilities;” and in § 52.39(a)(1), and § 52.39(c)(1)(i)-(iii) and (v), regarding the finality of ESP determinations, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

Transfer of an ESP

Comment 012-3: A commenter noted that the NRC proposes to add a new § 52.28 providing that transfer of an ESP will be processed under 10 C.F.R. § 50.80. The commenter does not object to this provision but recommends that the Commission should clarify when transfer of an ESP is necessary.

In particular, the commenter stated that the Commission should clarify that a COL applicant will remain able to reference an ESP held by another entity without any need for a transfer of the ESP. The commenter noted that under the current regulations, a COL may reference an ESP without regard to whether the COL applicant and the ESP holder are identical. [See, e.g., 10 CFR § 52.73.] The commenter continued to state that the ability of a COL applicant to reference an ESP held by another entity is clearly intended by the current rules. The commenter noted as an example that 10 CFR 52.25(a) provides that if an ESP contains a Site Redress Plan, “the holder of the permit, or the applicant for a construction permit or combined license who references the permit” may perform certain preconstruction activities. The commenter stated that if an ESP could only be referenced by its holder, the words quoted above would be meaningless, and it is axiomatic that laws must always be interpreted so as to give meaning to all words. [See, e.g., *Private Fuel Storage, LLC, (Independent Spent Fuel Storage Installation)*, CLI-02-29, 56 NRC 390, 397-98 & n.27 (2002). See also *United States v. Alaska*, 521 US 1, 59 (1997); *Rosenberg v. XM Ventures*, 274 F.3d 137, 141 (3d Cir. 2001).] The commenter continued to state that it makes sense that a COL holder should be able to reference an ESP held by another entity, because an ESP is essentially only a site suitability determination.

The commenter asserted that allowing this flexibility is very important to efficient proceedings, because it is possible that state approvals shortly before or after a COL filing could result in some entity other than the ESP holder being chosen to become the COL applicant. The commenter noted as an example that an ESP might be held by a regulated utility, but subsequent deregulation might require divestiture of generating capacity and result in some other entity submitting the COL application. The commenter noted that state approvals for a certificate of need might result in a change in the entity to construct and operate a plant, and construction financing requirements could also dictate the choice. The commenter suggested that if an ESP had to be transferred to accommodate such changes, the filing of a COL application might be unnecessarily delayed, or if already filed, the review of the COL might be disrupted.

The commenter noted that the NRC previously stated that they “would not permit a license applicant to reference an early site permit which it does not hold (or has rights to the permit contingent upon a NRC decision to issue a license whose application references the early site permit). To otherwise permit referencing of an early site permit by a non-holder would destroy the commercial value of the permit, and would prevent any entity from seeking an early site permit. This would frustrate the Commission’s regulatory objective of providing early regulatory approval of siting, emergency preparedness, and environmental matters.” [68 FR 40026, 40037 n.2, July 3, 2003] The commenter stated that, while the first sentence quoted above is not clearly worded, the commenter understands it to mean that a COL applicant may reference an ESP held by another entity if the ESP holder has given it the right to do so. The commenter stated that where a COL applicant and the ESP holder are affiliates, and the ESP holder has permitted the COL applicant to reference the ESP, the commercial value of the ESP would not be destroyed. The commenter asserted that consequently, a transfer of the ESP is unnecessary and all that should be required is a showing in the COL application that the ESP holder has consented to the reference of its permit.

Accordingly, the commenter recommended that in the Supplemental Information accompanying any final rule, the Commission should explain that the section governing transfers of ESPs does not signify that only an ESP holder may reference an ESP. Rather, the commenter suggested that transfer of an ESP is only necessary when responsibility for amending or renewing the permit changes. [See, e.g., 10 CFR 52.29(a) (“... the permit holder may apply for a renewal of the permit.”).]

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

New Requirements for Preconstruction Activity Authorization

Comments 012-4 and 013-1: Several commenters stated that their organizations are concerned that certain provisions of the proposed rule would make preconstruction work a licensed activity. The commenters respectfully submitted that these changes are unnecessary, would institute new standards and requirements for early site permitting, and would be bureaucratic and burdensome. The commenters noted that under the current rules in 10 CFR 52.25(a), an ESP holder may perform certain preconstruction activities if it has provided a site redress plan and if the NRC’s EIS prepared for the permit has concluded that the activities will not result in any significant environmental impact which cannot be redressed. The commenters stated that therefore, no specific authorization is currently required. The commenters noted that the proposed rule would delete this provision, and would allow preconstruction activities only if and to the extent specifically authorized in an ESP. [See 71 FR 12892 (proposed Section 52.24(c))]

The commenters stated that these changes are inappropriate for a number of reasons. First, the commenters stated that they elevate preconstruction work to a licensed activity. The commenters asserted that this is inconsistent with the original intent of the NRC rules, which was to designate those activities that did not require a construction permit.

The commenters noted that 10 CFR 50.10(b), promulgated in 1960, excluded site excavation, preparation of the site for construction, construction of roadways, railroad spurs, and transmission lines, and construction of non-nuclear facilities and temporary buildings from the definition of construction. [See 25 FR 8172, 1960] In 1968, driving of piles was added to the list of activities that could be performed without a construction permit. [See 33 FR 2381, 1968] The commenters noted that after the promulgation of NEPA, the NRC added 10 CFR 50.10(c) to provide for environmental review prior to “commencement of construction,” which it redefined. [See 37 FR 5745, 1972] The commenters also noted that the Commission later amended its rules again to allow the NRC staff to authorize limited work, including authorization to perform the activities in 10 CFR 50.10(e)(1), after completion of the hearings on NEPA and site suitability issues. The commenters noted that in the rule promulgating those changes, the Commission explained its position on this issue. [See 39 FR 14506, 14507, 1974]

The commenters stated that consequently, the activities specified in 10 CFR 50.10(e)(1), which are the activities that an ESP holder is permitted to perform by rule under 10 CFR 52.25(a), are not activities that must be licensed under the Atomic Energy Act. The commenters asserted that, as evidenced by 10 CFR 50.10(b), they do not have to be authorized by a construction permit (and therefore also do not have to be authorized by an ESP). The commenters stated that what the NRC rules are intended to do is to ensure that such activities are not performed prior to completion of the NEPA review, and where an ESP has been issued, that is obviously the case.

The commenters stated that it is not necessary to specify such activities in order to define the work that an ESP holder may perform. The commenters noted that under the current rules in 10 CFR 52.25(a), an ESP holder may only perform preconstruction activities that have been evaluated in the NEPA EIS and determined to involve no significant environmental impact that cannot be redressed. The commenters stated that therefore, the final EIS defines the scope of activities that may be performed under the rules. If an ESP applicant does not want authority under 10 CFR 52.25(a) to perform certain activities within the scope of 10 CFR 50.10(e)(1), it can exclude such activities from the scope evaluated in its application, and the NRC staff would then not evaluate the impacts of such activities in its EIS.

One of the commenters also stated that pre-construction activities currently outlined in 10 CFR 50.10(b) and 50.10(e)(1) should be authorized without the need for a prior permit or LWA. NRC approval of pre-construction activities should focus solely on matters pertaining to safety.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to these comments.

New Requirements for Preconstruction Activity Authorization

Comment 012-5: A commenter asserted that elevating the preconstruction activities to ones that can only be performed if authorized by a license creates a scheme that is more bureaucratic and limiting than the procedures not only under the current Part 52 rules, but also under the old Part 50 provisions. The commenter stated that this creates numerous undesirable consequences. The commenter noted as an example that under the existing rules in 10 CFR 52.25(a), preconstruction activities may be performed either by an ESP holder or by an applicant for a COL referencing an ESP (i.e., the ESP holder and COL applicant do not have to be the same entity). The commenter asserted that by requiring a specific authorization in the ESP and by deleting 10 CFR 52.25(a), the proposed rule would eliminate this flexibility.

NRC Response: The Commission disagrees with this comment. Under the former provisions of 52.17 and 52.22, the early site permit would itself authorize the LWA activities described in § 50.10(e)(1). The Commission does not see how the provisions in the March 2006 reduced the flexibility of either the early site permit holder or the combined license applicant. In any event, after consideration of public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The Commission believes that the commenter's concerns have been largely rendered moot by these changes.

New Requirements for Preconstruction Activity Authorization

Comment 012-6: A commenter stated that the proposal to require specific authorizations in the rule for preconstruction activities changes the fundamental nature of the ESP from a site suitability determination to one that authorizes activities, and thus implicates certification requirements under the Clean Water Act (CWA) and the Coastal Zone Management Act (CZMA). The commenter noted that Section 401 of the CWA prohibits the NRC from issuing a license to conduct an activity that may result in a discharge into navigable waters unless the state certifies that the discharge complies with certain requirements under the Act or waives certification. [See 33 USC Section 1341(a).] The commenter also noted that Section 307 of the CZMA requires, for any federal license to conduct an activity affecting a coastal zone, a certification that the activity complies with the enforceable policies of the state's Coastal Zone Management Program. [See 16 USC Section 1456(c)(3).] The commenter stated that under the current regulations, preconstruction activities are activities that do not have to be licensed, and therefore these certification requirements should be inapplicable. This does not mean that state review is avoided. Construction runoff is a point source discharge requiring a National Pollutant Discharge Elimination System permit from the state. However, this permitting would occur when the company proposing to build a new plant is ready to commence preconstruction activities, rather than at the ESP stage when such review may be premature. The commenter stated that under the proposed rule, either certifications or waivers would have to be obtained from the state, which can be very difficult when the schedule for preconstruction activities is unknown (as is the case for an ESP which remains in effect for 20 years).

NRC Response: The Commission disagrees with this comment. An applicant for an ESP under former § 52.17 could request the authority to conduct the LWA activities described in § 50.10(e)(1), which were considered, under the provisions of the former rule, to be construction activities. Hence, as other commenters recognize, NRC permission in the form of

an ESP specifically authorizing such activities is required. To the extent that the commenter is arguing that the NRC should not consider these activities to be construction and therefore should not require NRC approval, the NRC agrees. This determination is reflected in the substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule.

New Requirements for Preconstruction Activity Authorization

Comment 012-7: A commenter stated that by turning preconstruction work into a licensed activity under the Atomic Energy Act, the proposed rule also adds new technical qualification requirements. The commenter noted that in particular, the proposed rule would amend the findings that the Commission must make for issuance of an ESP to include a finding that “the applicant is technically qualified to engage in any activities authorized.” [See 71 FR 12892, proposed § 52.24(a)(4)] The commenter stated that such a requirement does not exist under the current rules, and indeed, preconstruction activities have never required such a finding. The commenter also stated that there are no applicable standards or guidance. The commenter asserted that it is anomalous to require technical qualifications for the activities currently permitted by 10 CFR 52.25(a), because no construction of safety-related structures is permitted.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to this comment .

New Requirements for Preconstruction Activity Authorization

Comment 012-8: A commenter noted that the proposed rule would require the proposed preconstruction activities to be identified and described in the site safety analysis report (SSAR). [See 71 FR 12891, proposed § 52.17(c)] The commenter noted that the rulemaking notice explains that this new section of the SSAR “would enable the NRC staff to perform its review of the request, consistent with past practice, to determine if the requested activities are acceptable under 10 CFR 50.10(e)(1).” [See 71 FR 12791] The commenter stated that alternately, 10 CFR 50.10(e)(1) allows these activities to be authorized if the staff has completed its EIS and if the Licensing Board has made its NEPA and site suitability findings. The commenter stated that there is no requirement for an NRC safety review in § 50.10(e)(1), and therefore there is no basis for the current proposal to require preconstruction activities to be discussed in the SSAR. The commenter asserted that, to the extent that the proposed rule may be intimidating that some additional safety review should be performed, without any specified standards or guidance, it would make the new licensing process more burdensome. It is possible that the NRC staff may be contemplating a review of preconstruction activities to evaluate potential impacts on existing units at multi-unit sites. As discussed in the next section, the licensees of existing units have authority, programs and procedures necessary to maintain safety and security at these sites, and the NRC staff has acknowledged that the preconstruction activities would not pose safety and security issues.

The commenter stated that rather than making the new licensing process more efficient and effective, these provisions would institute new standards, reviews, and approvals on to the process. The commenter recommended that if the NRC does proceed with the promulgation of these changes, it should apply such changes only to ESPs applied for after the effective date of the new rule. The commenter stated that the current 10 CFR 52.25 should remain in effect and applicable to the ESPs already applied for.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to these comments.

New Requirements Related to Limited Work Authorizations

Comment 007-30: Several commenters stated that the proposed rule contains new requirements that place unnecessary new limits and burdens on COL applicants and ESP holders that wish to obtain Limited Work Authorizations (LWAs) and perform pre-construction site preparation activities. The commenters suggested that there may be situations in which the ESP holder did not include a site redress plan in its ESP application. The commenters stated that if, as they proposed in their May 25, 2006, partial comments (comment letter 004), NRC determines that future applicants need not obtain NRC authorization to perform LWA-1 activities, then this omission will become moot or cease to be significant.

One commenter added that the changes proposed in the May 25, 2006, letter on preconstruction activities/LWAs are very important to the commenter because they could accelerate a plant's construction completion date by more than a year. The commenter clarified that specifically, existing constraints on pre-construction activities that are not safety-related (LWA-1 activities) are not required by existing statutes. The commenter stated that therefore, LWA-1 activities should not require NRC authorization. The commenter also stated that the authorization of certain limited pre-construction activities that have a nexus to nuclear safety (LWA-2 activities) should not have to await the issuance of a final environmental impact statement (EIS).

The commenters went on to suggest that alternatively, if the Commission determines that a site redress plan continues to be a prerequisite for LWA-1 and LWA-2 activities, the NRC should revise its regulations to authorize ESP holders (including those whose ESP applications were under review at the time the final rule becomes effective) the flexibility to submit a site redress plan if they did not do so originally, so that they may conduct LWA activities.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to substantially revise provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these proposed revisions. Accordingly, no response is necessary to these comments.

5.3.3 Subpart B – Design Certification

Terminology

Comment 001-1: A commenter noted that throughout 71 FR 12782 the terms “transients,” “transient conditions,” “limiting transient,” “operational transients” are used to mean “anticipated operational occurrences.” The commenter stated that, with the exception of the term “Anticipated Transients Without Scram,” no other “transient” term is defined in 10 CFR or the standard review plan. The commenter indicated that 10 CFR Part 50, Appendix A, does specifically define “anticipated operational occurrences,” and the general design criteria correctly refer to “anticipated operational occurrences.” The commenter suggested that to assure consistency throughout the regulation, the Statements of Consideration, and Appendix A, (except for anticipated transients without scram) all “transient” terms should be changed to “anticipated operational occurrences.”

NRC Response: Revising the term “transient” throughout Part 50 is not within the scope of the Part 52 rulemaking. No changes have been made to Part 50 as a result of this comment.

Comment 001-2: One commenter pointed out that proposed § 52.47(a)(16) applies “SSCs important to safety” to Part 50, Appendix S, but Appendix S applies to safety-related SSCs, not all SSCs important to safety. Thus, the term “SSCs important to safety” should be replaced with “safety-related SSCs.”

NRC Response: The NRC agrees with the comment, and has modified the language in § 52.47(a)(20) in the final rule.

Comment 001-3: One commenter believed that proposed § 52.47 should require criteria for determining which non-safety-related SSCs are considered/categorized as important to safety.

NRC Response: The NRC does not agree that creating a definition of SSCs that are important to safety is within the scope of the Part 52 rulemaking. No changes have been made as a result of this comment.

Comment 001-4: One commenter suggested that in Subpart B – Standard Design Certifications, the term final safety analysis report (FSAR) should be replaced with the term standard safety analysis report (SSAR). The term FSAR is used in Subpart C – Combined Licenses to refer to a different submittal.

NRC Response: The NRC disagrees with this comment. In the past, design certification applicants have submitted SSARs, which were effectively the FSAR for the purpose of meeting the information requirements of the former § 52.47. The FSAR in Subpart C is not a different submittal and the FSAR for design certification will become part of the FSAR for a combined license. Therefore, future design certification applicants should submit an FSAR, as required by § 52.47(a).

Comment 001-5: One commenter notes that proposed § 52.47(a)(26) states that an application must include “an evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application.” The

commenter suggests that “(formally approved and issued)” should be added after “revision in effect” to minimize the current confusion about which SRP versions apply.

NRC Response: The NRC does not agree that the phrase “revision in effect” needs to be clarified.

Comment 001-6: One commenter believed that the articles of consideration for Part 52 or § 52.47 should state “(a) Conformance with draft SRP criteria is strictly voluntary, as long as the regulations are complied with.” This is because the issue of which SRP version applies causes much confusion.

NRC Response: The NRC does not agree with this comment. The evaluations of the plant design against the SRP criteria will facilitate future design reviews.

Comment 001-7: One commenter believed that the articles of consideration for Part 52 or § 52.47 should state “(b) The addressing of SRP criteria requiring site-specific and/or as-build equipment information should be the responsibility of the Combine License holder, and thus, should be deferred until after the start of construction.” This is because some information requested by an SRP cannot be provided until a site is finalized or a component is manufactured.

NRC Response: The NRC does not agree with this comment. The SRP is a guide for the NRC staff’s review of many different types of applications, including license amendments. The applicability of the SRP criteria is determined based upon the type of review being performed.

Comment 001-8: One commenter believed that the articles of consideration for Part 52 or § 52.47 should not apply to SSCs that meet the criteria in paragraph (c) of the comment.

NRC Response: The NRC does not agree with this comment. The applicability of various sections of the SRP are determined on an application-specific basis.

Comments 001-9, 001-10, and 001-11: One commenter suggested that proposed Part 52 should specify (a) the criteria for determining inspections, tests, analyses, and acceptance criteria (ITAAC), (b) that ITAAC are not required for confirmations that are covered by technical specifications surveillances, and (c) the categories of SSCs (e.g., safety-related SSCs or all SSCs important to safety as defined on a basic design basis) for which ITAAC should be provided. The levels of detail between ABWR ITAAC and the AP1000 ITAAC are not consistent and specific criteria for determining ITAAC are needed to ensure consistency. Technical specifications (TS) surveillances could perform the same function as the ITAAC, and having an ITAAC confirmation/validation a design feature or function already covered by TS surveillance(s) is redundant, and thus, unnecessary. Addressing SSCs that have no affect on safety (1) convolutes the understanding of a plant’s safety basis, (2) wastes industry and NRC resources for their generation and review, and (3) will eventually result in license amendment requests for non-safety changes that would otherwise be licensed under § 50.59, and thus, wastes additional NRC resources.

NRC Response: The NRC does not agree with these comments. First of all, the requirement for specifying ITAAC is already set forth in 10 CFR 52.97(b). Second, ITAAC is a verification

process for determining whether a plant should be authorized to operate. Whereas, technical specifications are operational requirements and they cannot perform the same function as an ITAAC verification. Third, ITAAC need to verify that the entire facility has been completed. Therefore, the scope of ITAAC covers the entire plant and the level-of-detail for ITAAC that verify structures and systems is proportional to the safety significance of those structures and systems. The level-of-detail for any particular ITAAC will vary for different designs. Finally, the criteria for license amendments, after the finding is made under § 52.103(g), are not dependent on ITAAC.

Comment 005-13: A commenter notes that on page. 12794 of the NOPR, the NRC describes its proposed process for allowing the Commission to make changes in design certification rules in 10 CFR Part 52. However, there is no discussion of the process by which the Commission would make a determination that, for example, a change to a DC rule would, in fact, constitute a reduction of regulatory burden. In addition, the provision that any such change would apply both to pending and planned COL applications and to plants that are currently operating ignores the fact that it is far easier and less expensive to make changes to “paper” designs than to an operating plant. Thus, “burden reduction” (which could be interpreted as including a cost-benefit evaluation) could not be assessed in the same fashion for operating and “potential” plants.

NRC Response: The NRC agrees with the commenter that the amount (if any) of burden reduction attributable to a proposed change in a design certification rule may differ for a hypothetical future license application referencing the design certification rule, as compared with an operating nuclear power plant referencing that design certification rule. Such issues will be addressed in the regulatory analysis (and possibly as part of the documentation for the Paperwork Reduction Act) that must be prepared for the proposed rulemaking, and will be considered by the Commission in determining whether to adopt the proposed change to the design certification rule by rulemaking. The Commission will be aided in these determinations by comments on the proposed rule that would amend the DCR. Licensees who believe that there would be little burden reduction (or, in fact, an increase in burden) attributable to a proposed change to a design certification rule will have the opportunity to submit such information to the Commission for its consideration as part of the notice and comment rulemaking process.

Comment 006-8: One commenter believed that it is inappropriate and unfair to apply provisions that are applicable to licensees to applicants for design certifications, given the fact that design certification applicants are not afforded the protections accorded to licensees under the law.

NRC Response: The Commission disagrees with the commenter that the proposed rule’s imposition on the design certification applicant of new regulatory obligations represents a fundamental shift in the nature of design certification which is “inappropriate...and unfair....” The choice of rulemaking versus licensing in design certification ultimately represents the Commission’s choice of the regulatory vehicle for providing its approval of a final reactor design. While it is true that the regulatory vehicle chosen will determine the manner in which regulatory obligations are imposed, the technical, regulatory and policy bases for the applicability of underlying NRC regulatory requirements exist regardless of the regulatory vehicle. For example, take the issue of reporting of defects in engineering on a reactor design. The public

health and safety need for prompt reporting to the NRC of such defects is the same regardless of whether the reactor design was submitted to the NRC for approval by license, or approval by rulemaking. That is why Section 206 of the Energy Reorganization Act of 1974, as amended, imposes reporting with regard to “any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended...(emphasis added).” The Commission rejects as untenable any argument that a rulemaking “imposing” the legal obligation of design certification applicants to report defects is inappropriate, or otherwise represents a “fundamental shift” in the nature of design certification.

The commenter did not identify the protections which are afforded to licensees under the AEA and APA but are not provided to design certification rulemaking applicants. Therefore, it is difficult for the Commission to address the commenter’s concerns. The one matter of which the Commission is aware of a difference between rulemaking versus licensing, is the protection of proprietary information. In a licensing proceeding proprietary information may be protected from disclosure in accordance with the applicable provisions of the Freedom of Information Act (FOIA). FOIA’s protections for proprietary information do not extend to information in a rule, or forming the bases for a rule; such information must ordinarily be disclosed in a rulemaking proceeding. However, this matter was thoroughly considered and addressed in the 1989 Part 52 rulemaking, and nothing in the 2006 proposed rule changes alters the Commission’s prior consideration of this issue with respect to design certification rulemaking. Moreover, although the commenter argues that “some of the proposed changes” are “not authorized by law,” the commenter does not identify the specific changes in the proposed rule falling into this category, which makes it impossible for the Commission to address the commenter’s concern on a specific basis. Nor does the commenter present any argument in support of this assertion or otherwise address the Commission’s discussion in the SOC for the proposed rule in which the Commission identified the statutory bases for the most significant obligations imposed on design certification applicants, namely, Parts 19 and 21.

For these reasons, the Commission has not made any changes to the final rule in response to the commenter’s suggestion.

Issues about SAMDAs

Comments 005-3 and 005-4: A commenter objected to the proposed requirement in § 52.47(b)(5) for design certification applicants to provide a separate environmental report that specifically addresses SAMDAs. Currently, a single analysis can be used to satisfy both the Part 51 NEPA-related requirement for a SAMDA assessment and the technical requirements of § 50.34(f)(1)(i). The commenter believed the proposed requirement (and other similar ones) should be deleted from the rule in favor of maintaining the process detailed in SECY-91-229. At a minimum, the environmental report should only be required if requested changes would cause a significant increase in risk.

NRC Response: The NRC does not agree with this comment. As stated above, SAMDA evaluations are required in order to achieve greater finality for the design features that are resolved in design certification rulemakings. Further, the NRC believes that the SAMDA environmental report should be separate from the final safety analysis report. Also, the risk assessment performed under § 50.34(f)(1)(i) is a subset of the design alternatives considered in the SAMDA evaluation. However, the NRC did revise the requirement for design certification

applicants [see § 52.47(b)(3)] to be consistent with the requirement in Part 51 (see § 51.55). In addition, the final rule is in conformance with the SRM on SECY-91-229, where the Commission approved the staff's recommendation to address SAMDAs for certified designs in a single rulemaking process that would consider both § 50.34(f) and the NEPA requirements in the design certification rulemaking.

Comments 005-6, 007-40, and 012-2: Several commenters believe that the requirements for a SAMDA evaluation in the proposed rule should be deleted. Instead, the NRC should initiate a rulemaking (rather than a plant-by-plant analysis) to generically determine that severe accidents in new nuclear plants are “remote and speculative” and that SAMDA evaluations are not required for new nuclear plants.

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

Comment 005-7: The requirement in 10 CFR 51.55 (p. 12882) for an applicant for an amendment to a DC to file a supplemental environmental report (ER) addressing changes in the outcome to a SAMDA assessment is far beyond the requirements that must be met for a licensee who wants to make changes to a plant licensed under 10 CFR Part 50. It would be preferable for this provision to be dropped altogether, but as a minimum, such an assessment should only be required if the requested changes would cause a significant increase in risk. Since the SAMDA assessment is a risk-based evaluation, it is reasonable to assume that design changes that do not increase plant risk would not change the result of a SAMDA assessment.

NRC Response: The Commission does not agree that the proposed provision in § 51.55 should be deleted or modified to limit the need to prepare an environmental assessment (EA) only if the requested changes would cause a significant increase in risk. An amendment to a design certification is a new rulemaking and, therefore, is a Federal activity or action under the National Environmental Policy Act. In implementing this provision of the rule, the Commission is limiting the environmental inquiry for a design certification rulemaking to an EA because the design certification rulemaking would not have a significant impact on the environment, and, furthermore, that the EA would be focused in scope to the consideration of SAMDAs. The Commission has determined that the potential significant impact on the environment from the certified design could only occur with the construction or operation of a nuclear power plant that references the design and such actions, such as the issuance of a combined license, would require the NRC to develop an environmental impact statement. Therefore, as stated in

§ 51.55, an applicant for a proposed amendment to a design certification must submit an environmental report that addresses SAMDAs. If the proposed amendment does not make changes to any portion of the design and the bases for the previous SAMDA analyses did not change, then the EA associated with the amendment to the design, which is a new design certification rule, can rely upon the earlier analyses (using tiering and incorporation-by-reference principles) and the staff will disclose that in its EA.

Comment 005-5: A commenter objected to the statement in the preamble that said SAMDAs are “alternative design features for preventing and mitigating severe accidents.” The commenter pointed out that the term itself does not include “prevention” of severe accidents, which is mentioned in § 52.47(a)(20).

NRC Response: The NRC disagrees with the commenter. Although the commenter is correct that the acronym, “SAMDA,” stands for “severe accident mitigation design alternatives,” the NRC has always understood the term to include design measures for the prevention of accidents. The NRC believes that consideration of severe accident prevention is prudent and consistent with NEPA, inasmuch as it is ultimately preferable to preclude the adverse environmental impacts from occurring through prevention of an accident, rather than tolerating a high probability of accident occurrence and instead attempting to mitigate the effects of the accident.

Concern about expanding scope of ITAAC

Comment 007-14: Several commenters noted that proposed § 52.47(b)(2) changes the scope of the ITAAC required for design certification from those needed to ensure conformance to the “design certification” to those needed to ensure that the plant conforms to the “design certification, the provisions of the Act, and the Commission’s rules and regulations.” The preamble explains that the proposed rule would conform to the requirement for acceptable inspections, tests, analyses, and acceptance criteria (ITAAC) with the Atomic Energy Act and the requirements in the current § 52.97(b). This clarification of the current language, which was a condensed version of the language in §§ 52.79(c) and 52.97(b), is intended to avoid any future misunderstandings. The commenters disagreed that this justifies the proposed change, or that the change is necessary to prevent “misunderstandings.” The language in Section 185.b of the Atomic Energy Act applies to COLs, not to design certifications. Given the smaller scope of a design certification, it is natural to apply different requirements to design certification ITAAC versus COL ITAAC. This proposed change could be misconstrued as expanding the scope of the ITAAC needed for design certification. Furthermore, it would be impossible for a design certification applicant to satisfy the literal language of this new provision, since the scope of the standard design does not encompass all of the design within the scope of the NRC’s rules and regulations.

NRC Response: The NRC does not agree with this comment. The clarification in § 52.47(b)(2) conforms with the AEA and provides the full and correct rule language for ITAAC, not the condensed version. It is important to remember that the design certification ITAAC will become part of the COL ITAAC. Also, this clarification will not be misconstrued with the requirement for the scope of design information needed for design certification, which is set forth in § 52.47(c). The requirements that are applicable to a certified design are defined by the scope of the design certification rule.

New Security Requirements for Design Certification and Design Approval Applicants

Comment 007-23: Several commenters noted that proposed 10 CFR§ 52.47(a)(24) and 52.137(a)(24) would specify that applications for a design certification or standard design approval must describe the design features needed to satisfy Part 73 regarding security. The commenters stated that the Supplementary Information for the proposed rule does not explain the need for or purpose of this proposed requirement as part of the current rulemaking. The commenters recommended that the Commission remove these proposed paragraphs from the current rulemaking and include appropriate provisions in a separate rulemaking specific to security design expectations.

The commenters stated that the proposed requirement is too broad and cannot be implemented as written. The commenters noted that many of the security design features required by Part 73 are outside the scope of the standard design and cannot be satisfied by a design certification applicant or an applicant for design approval. The commenters went on to state that a number of security design features will be site-specific and will be the responsibility of the COL applicant. The commenters recommended that therefore, at the very least, the language in the proposed rule on this point should be modified to indicate that applicants for design certification and design approval need only address those security design features that are within the scope of the standard design.

The commenters understand that there are five security rulemakings being developed. The commenters stated that any additional security requirements should be deferred to the security rulemakings and not included in a rulemaking on Part 52. The commenters stated that the security design expectations for new reactor licensing activities are the topic of a separate rulemaking activity which has been approved by the Commission in the Staff Requirements Memorandum on SECY 05-120 (Sept. 9, 2005). The commenters recommended that Part 52 should reference Part 73 and the other NRC requirements relating to security.

NRC Response: The NRC agrees with the comments. The paragraphs mentioned are now reserved.

Comment 007-24: Several commenters noted that proposed § 52.54(b) would require the design certification rule to specify “design characteristics.” Section 52.47 already requires that characteristics of the standard design be identified in the design certification application. In particular, the design characteristics are identified in the Design Control Document, which is incorporated by reference in the design certification rule. The commenters felt that it is unclear what more, if anything, is contemplated by the proposed rule, and anything more would be superfluous and confusing.

NRC Response: The NRC disagrees with this comment. The NRC wants to specifically identify site parameters and design characteristics in order to facilitate future comparisons with site characteristics and design parameters specified in an early site permit. The NRC staff will use its experience with the current early site permit reviews to determine what an appropriate list of design characteristics will be for future design certification reviews.

Submittal of FSAR or DCD

Comments 007-61 and 001-12: Several commenters pointed out that proposed § 52.47(a) would require that the DC application contain an FSAR. However, the NRC has required all design certification applicants to date to submit a Design Control Document (DCD), which largely duplicated the information submitted as part of the safety analysis report. Furthermore, it is the current practice of design certification applicants to submit a DCD and not a FSAR. To avoid burdensome and redundant submittals, incorporate an important design certification “lesson learned,” and conform to current NRC practice, proposed § 52.47(a) should refer to a DCD rather than an FSAR, or reflect that a DCD is effectively the FSAR for the purpose of the regulations.

NRC Response: The NRC disagrees with this comment. The requirement to submit an FSAR is not a redundant submittal. In the past, design certification applicants have submitted DCDs, which were effectively the FSAR for the purpose of meeting the information requirements of the former § 52.47. The reason that the DCD terminology was used in the past no longer exists and that terminology will not be needed in the future. Therefore, future design certification applicants should submit an FSAR, as required by § 52.47(a).

Comment 007-76: Several commenters supported proposed §§ 52.43, 52.45, and 52.47(b)(4).

NRC Response: No response necessary.

Some of the New Requirements Would Inappropriately Apply to Non-Light Water Reactors

Comment 020-1: The new requirements are written generically and would apply to all types of new reactors, including reactor types beyond light water reactors (LWRs). However, in some cases, the genesis of the requirements specifically arose and is applicable to LWRs only, and it would be inappropriate to apply the new requirements to non-LWRs. For example:

- The requirement for a design certification applicant to compare its design against the SRP should only be applicable to LWRs, since the SRP was developed and is specifically applicable only to LWRs. Applicants for other types of reactors, such as high temperature gas cooled reactors, should not be required to prepare a comparison against the SRP.
- The requirement for an evaluation of features to prevent and mitigate core melt accidents appears to reflect the intent of the NRC to codify the severe accident provisions in SECY-93-087. However, SECY-93-087 pertained only to light water reactors. Furthermore, core melt accidents are not credible in some Generation IV reactor designs, such as high temperature gas cooled reactors (HTGRs). In particular, HTGRs are not susceptible to the type of events specifically listed in the proposed rule, such as steam explosions, high-pressure core melt ejection, and hydrogen detonation. Therefore, there is no reason to require such designs to include an evaluation of features to prevent and mitigate core melt.
- Proposed Sections 52.47(a)(5), (6), (8), and (12) state, without limitation or qualification, that design applicants must meet the requirements in certain NRC regulations.

However, the regulations in question only pertain to LWRs. Thus, the proposed rule creates the potential for confusion, because the proposed rule might be erroneously construed as requiring all reactor types (not just LWRs) to satisfy the cited regulations. Therefore, we recommend that the proposed sections cited above be revised either to refer to LWRs (or, in some cases, pressurized water reactors) or to add the phrase "as technically relevant".

In short, several provisions in the proposed rule are inappropriate as applied to non-LWRs. At the very least, the NRC should modify those provisions to limit their applicability to LWRs.

NRC Response: The NRC agrees that there are various technical requirements, including those identified by the commenter (e.g., evaluation of core melt accidents, hydrogen detonation), which may not be applicable to non-LWR designs. However, it was not within the scope of the Part 52 rulemaking to evaluate the potential technical inapplicability of the Commission's regulations to non-LWR designs. To accomplish this task would have further lengthened the period of time necessary to complete this rulemaking. Such an expansion of the scope of this rulemaking seemed unwarranted, in light of other Commission regulatory activities with the goal of developing the appropriate technical infrastructure for advanced and non-LWR designs. These include the Technology Neutral Licensing Framework, and interactions with DOE on advanced burner reactor design. The Commission notes that most of the requirements in Part 50 are, for the most part, technology neutral, and have been applied in past AEC/NRC licensing actions for non-LWR designs, such as Peach Bottom, Fort St. Vrain, and the Clinch River Breeder Reactor. At least one potential combined license applicant (Exelon) has concluded that most of the technical requirements in Part 50 would be applicable to non-LWR designs that they were considering for a new nuclear power plant. Each of the current standard design certification applicants identified several technical requirements which they believed should not be applied to their design. The Commission provided dispensation from compliance with these requirements by including appropriate exemptions in each of final design certification rules. The same process may be used by future applicants for design certifications, including applicants for certification of non-LWR designs. Accordingly, the Commission has not adopted the commenter's proposal, and no change to the rule was made as a result of this comment.

The Commission also agrees with the commenter that the current SRP is written based upon LWR designs. However, the Commission disagrees with the commenter that applicants for other types of reactors, including the PBMR, should not be required to evaluate their designs against the SRP. First, there are a large number of areas within the SRP that are "technology-neutral" in the sense that the Staff review guidance applies regardless of the technology of the reactor under review. Second, the SRP is not a requirement, and indeed, the regulation simply requires the applicant to identify where the design has diverged from the guidance in the SRP. The purpose of this requirement is one of resources and planning: it allows the NRC staff to estimate areas which may require special resources, and a greater period of time, to perform an adequate safety review. The commenter did not set forth more specific reasons why the underlying goals of the requirement for evaluation against the SRP would not be served in the case on non-LWR designs.

5.3.4 Subpart C - Combined License

Incorporation of ESP ITAAC

Comment 003-13:⁴ Commenters noted that § 52.99(d) incorrectly referred to the ESP ITAAC. Commenters argued that when the COL is issued, it incorporates the ESP ITAAC, meaning the ESP would no longer be effective with respect to that COL.

NRC Response: The NRC agrees that the proposed language in § 52.99(d) that referred to requesting variances to ESP ITAAC after the COL is issued is inconsistent with rule language in other sections of Part 52 [e.g., § 52.39(d)]. Therefore, the NRC has adopted the commenters suggestion to delete references to ESP ITAAC and ESP variances from § 52.99(d).

ITAAC Completion

Comment 007-42: Several commenters noted that for ITAAC completed within the last 180 days before fuel load, proposed Section 52.99(c) would require the COL holder to notify the NRC within 10 days of successful ITAAC completion. The commenters stated that this requirement is unnecessary and recommended that it should be deleted. The commenters noted that the licensee will be highly motivated to notify the NRC of successful ITAAC completion as quickly as possible so as to trigger the NRC's ITAAC verification process.

The commenters stated that processes for expediting ITAAC verification during the critical last 6 months before fuel load should be considered in an integrated and comprehensive way outside the rulemaking context. The commenters asserted that rule changes are not necessary. Rather, the commenters recommended such processes be discussed as part of the ongoing joint industry-NRC ITAAC Demonstration Project. The commenters intend to document common understandings about ITAAC implementation and verification, including special processes for managing the ITAAC verification in the last 6 months before fuel load, in NEI 06-01, "COL Implementation Guideline."

NRC Response: The NRC agrees, in part, with this comment. The NRC has decided that it does not need to specify a time period for the licensee to notify the NRC of the successful completion of ITAAC and the proposed requirement for a 10-day notification was deleted from § 52.99(c). However, the licensee's notifications will affect the timing of the NRC's conclusion's regarding whether ITAAC have been successfully completed. In addition, the NRC has added a new provision to § 52.99(c) dealing with the last 6 months before initial fuel loading. This new provision is discussed in Section V.C.8.b of the "Supplementary Information."

Comment 013-5: A commenter recommended that the NRC should provide clear guidance for verifying completion of ITAAC. The commenter noted that such guidance is necessary given the central importance of ITAAC to the Part 52 licensing process, during which the Commission may find, in deciding whether to issue a COL, that ITAAC criteria have been satisfied and may be excluded from the COL (proposed 10 CFR § 52.97(a)(2)). The commenter stated that the

⁴Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI's comments submitted on May 25, 2006. Therefore, all of these commenters are included in each of NEI's May 25, 2006 comments (comment number 003). For simplicity, these comment numbers are not repeated in this document for each comment.

recommended guidance would include clarification on expediting ITAAC verification and on special processes for managing ITAAC verification in the last 6 months prior to fuel load, pursuant to the ongoing industry-NRC joint discussions and as described in NEI 06-01, "COL Implementation Guideline."

NRC Response: The NRC agrees with this comment and intends to issue regulatory guidance on the process for completing ITAAC. The NRC notes that the information that is necessary to demonstrate that ITAAC have been successfully completed will be the same before and after issuance of the combined license.

Comment 007-67: Several commenters pointed out that proposed § 52.47(b)(4) provides that ITAAC related to verifying compliance with interface requirements may be performed "either in the plant or elsewhere." The commenters recommended also adding the language "either in the plant or elsewhere" to §§ 52.47(b)(2) and 52.80(b) of the final rule.

NRC Response: The NRC disagrees with this comment. Inclusion of the statement "either in the plant or elsewhere" in the rule language is not necessary and the phrase has been deleted from the final rule language. The NRC recognizes that some testing, i.e., type tests, will be performed outside of the plant and these tests will be identified in the ITA column of the ITAAC tables. Also, tests and inspections may be performed at the locations where the components are fabricated. The tests and inspections that need to be performed under as-built conditions should be identified in the ITAAC or supporting documentation.

Section 52.103 Hearings

Comments 003-14, 003-4, 003-15, and 003-16: Several commenters stated that the hearing procedures described in § 52.103 and Part 2 need to be modified. Commenters believed the NRC should specify that § 52.103 hearings (the "ITAAC hearing") would be legislative hearings under Subpart O of Part 2. Commenters preferred the use of Subpart O over Subpart N because: (1) Subpart N contemplates a hearing that is not expected to require more than two days to complete, and (2) Subpart N requires all parties at the proceeding to agree the hearing should be conducted under that Subpart. Commenters noted that the "non-adversarial" nature of Subpart O-type legislative hearings (See 69 FR 2182, 2192, January 14, 2004) (NRC final rule amending rules of practice in 10 CFR Part 2) made them well-suited to the development of "legislative facts," viz., general facts which help a decisionmaker decide questions of policy and discretion."

To support the use of this type of hearing, commenters argued a legislative hearing would be consistent with § 189.a.(1)(B)(iv) of the Atomic Energy Act of 1954, as amended (AEA), and would meet the NRC's obligation under 10 CFR 52.103 to provide an opportunity for a hearing on whether the inspections, tests, analyses, and acceptance criteria for the new nuclear facility had been satisfied. Commenters stated that the NRC was required to hold formal, on-the-record hearings under the Administrative Procedure Act only if the agency's governing statute, the AEA, mandated such formal hearings. Commenters claimed the AEA did not mandate formal, on-the-record hearings for COL applications under 10 CFR Part 52 § 185.b of the Act. Commenters stated the NRC will conduct initial licensing hearings for COL applications under 10 CFR Part 2, Subpart L (informal hearing procedures). Commenters stated the AEA does not require formal, on-the-record hearings for the 10 CFR 52.103(d) ITAAC hearing. Commenters

referenced AEA § 189.a.(1)(B)(iv) and argued the language of NRC regulations in § 52.103(d) was essentially identical to this statutory provision. Commenters noted the AEA narrowly focuses the § 52.103 hearing opportunity on “whether the facility as constructed complies, or on completion will comply, with the acceptance criteria of the license” (See AEA § 189.a.(1)(B)(I)). Commenters contended that legislative hearings would be appropriate for resolving disputes regarding ITAAC satisfaction given the objective nature of most of the ITAAC. Commenters recommended changes be implemented by either: (1) issuing an order in each licensing proceeding, or (2) codifying the change by amending the language of existing 10 CFR Part 2, Subpart O (including §§ 2.1500 and 2.1502) to specify that Subpart O legislative hearings would be used to meet the NRC’s obligation under 10 CFR 52.103(d) to hold a hearing leading to the issuance of findings required under 10 CFR 52.103(g).

Commenters proposed that the NRC modify its hearing process to provide that, in deciding whether to grant a request for a hearing pursuant to § 52.103, the presiding officer first determine whether a contention was exempt from adjudication under § 554(a)(3) of the Administrative Procedure Act (APA) (5 U.S.C. § 554(a)(3)) and § 185b. of the AEA. Commenters noted that: 10 CFR 52.103(b) provides that a request for hearing under § 52.103(a) must show, prima facie, that (1) one or more of the acceptance criteria in the COL have not been or will not be met, and (2) the specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety. Commenters explained that APA § 554(a)(3) exempts from APA formal adjudication requirements those matters in which decisions “rest solely on inspections, tests and elections.” Commenters argued that the scope of the § 554(a)(3) exemption has generally been construed to include “technical facts ... as to which administrative hearings have long been thought unnecessary” and situations where an agency relies on the “judgment” of a tester or inspector. [Door v. Donaldson, 195 F.2d 764 (D.C. Cir. 1952); see also Attorney General’s Committee on Administrative Procedure, Final Report to President and the Congress, at 37 (1941) (noting that “resort to formal procedures... is not desired or utilized ... because it gives no added protection”); S.Rep. No. 752, 79th Cong., 1st Sess. 16 (1945) (exempting inspections, tests, and elections “because those methods of determination do not lend themselves to the hearing process”).]

Commenters believed that the APA § 554(a)(3) exemption relieves the NRC of the obligation to conduct any hearing under § 52.103 when the question of whether a new facility complies with an ITAAC can be decided solely on the basis of inspections or test results. To validate this belief, commenters noted that in *Union of Concerned Scientists v. U.S. Nuclear Regulatory Commission*, the Court acknowledged that Congress did not intend to require a hearing where it would serve no purpose, though exemption from AEA was not an exemption from APA § 554 procedures. (735 F.2d 1437, 1449 1450, D.C. Cir. 1984).

Commenters suggested that to remain consistent with APA § 554(a)(3), the NRC could exclude those specific “inspections, tests, and analyses” referenced in AEA § 185b. that rely solely on detailed, objective, or self-implementing acceptance criteria that do not lend themselves to the hearing process. Commenters stated that the NRC has in fact taken such action in the past (see November 20, 2003, NRC letter to NEI on combined license topic COL-5 concerning the 10 CFR 52.103 hearing process, p. 4). Commenters claimed that by limiting the scope of § 52.103 hearings to those ITAAC that actually had a component amenable to the informal hearing process, the NRC could more efficiently focus the pre-operational hearing process, save time by focusing on those ITAAC that involve issues that fall outside the APA exception,

and promote stability in the licensing process. Commenters claimed the position they were advocating was consistent with principles acknowledged by the NRC when it promulgated the original 10 CFR Part 52 (54 FR 15372, 15380, April 18, 1989). Commenters requested that the NRC not prejudge whether acceptance criteria raised under § 52.103 would be “self limiting.” Commenters suggested that to assure correct identification of which ITAAC were susceptible to resolution based solely on the results of tests and inspections, and thus should not be adjudicated, the NRC could: (1) delegate this determination to the NRC staff with technical expertise, (2) make determinations on a case-by-case basis, or (3) allow the presiding officer in the § 52.103 hearing to decide.

NRC Response: The Commission disagrees with the commenter’s suggestion that the final rule should require the use of subpart O hearing procedures. It is premature, given the lack of any experience in the use of subpart O procedures, as well as the lack of any experience in ITAAC hearings under § 52.103(g), to require by rule the use of these procedures. The Commission is not adverse to considering the use of subpart O procedures in a § 52.103 hearing (a matter for which the Commission declines to express an opinion at this time), and if so, whether Commission direction should be provided by generic guidance, or through case-specific Commission action. However, the Commission does not believe it to be prudent to require the use of those procedures in a rulemaking. Accordingly, the Commission declines to adopt the commenter’s proposal, and no change to any part of the final rule has been made as the result of the comment.

The Commission agrees with the commenter that Section 554(a)(3) exception of the Administrative Procedures Act may be used to in appropriate circumstances to avoid a § 52.103 hearing on whether a specific ITAAC (or portion of an ITAAC) has been satisfied. However, as the commenter notes, there are many alternative approaches for the NRC to make the determination of which ITAAC fall within the ambit of the APA exception. See May 25, 2006 NEI letter, p. 14. There has never been a § 52.103 hearing, so there is no applicable experience that the Commission could draw upon when formulating a generic rulemaking requirement. None of these alternatives (and other alternatives identified within the NRC) were discussed in the SOCs for either the 2003 or 2006 proposed rules. Adopting by rule a particular approach for invoking the Section 554(a)(3) exclusion, under these circumstances, is likely to result in adverse public assessments of the Commission’s actions. Finally, the need for resolution of this issue as part of this rulemaking is not clear, given that such hearings are unlikely to occur until well into the next decade. Accordingly, the Commission concludes that adoption of detailed rulemaking requirements governing the use of the Section 554(a)(3) exception in this final rulemaking would not be prudent.

New Requirements Applicable to COL Amendments

Comment 007-26: Several commenters noted that proposed 10 CFR 52.98(a) states that “after issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license which are not derived from a referenced standard design certification or manufacturing license, except in accordance with the provisions of § 52.103 or § 50.109 of this chapter, as applicable.” Overall, the commenters support the provisions in proposed § 52.98. The commenters stated that in particular, the intent of proposed § 52.98(a) appears to be appropriate, since it would restrict the Commission’s

unilateral ability to impose changes without the appropriate justification under the backfit rule in § 50.109. The commenters continued, and asserted that it appears that § 52.98(a) as written would not allow the Commission to make a change at the request of the COL holder unless the change meets the backfit rule.

The commenters noted that the December 27, 2005, NRC staff response to the Commission's Staff Requirements Memorandum on the proposed revisions to Part 52 states that it is not the intent of the NRC to impose the backfit criteria on license amendment requests by a COL holder. The commenters stated that in contrast the actual language used in the proposed rule does not reflect that intent. The commenters recommended that the proposed provision should be modified to clarify that the NRC may issue license amendments at the request of the licensee without the need for the licensee to demonstrate that the backfit criteria are satisfied.

NRC Response: The Commission does not agree with the commenter's position that a change to § 52.98(a) is needed to clarify that the Commission may issue an amendment requested by a combined license holder with respect to matters which are not derived from a referenced standard design certification or manufacturing license, without meeting the backfit criteria in §52.103 or § 50.109. Paragraph (a) is meant only to address limitations on the Commission's imposition of changes to the license (similar to § 52.39(a) for ESPs). Other provisions address the licensee's ability to request changes to the COL, most notably, § 50.90 and §§ 52.98(b), (c), and (d). However, even if one were to interpret this language as requiring compliance with the backfitting provisions in 50.109, the Commission has long interpreted the term, "backfitting," under § 50.109 as excluding voluntarily-initiated licensee requests for, inter alia, license amendments. Accordingly, there is no need to clarify the language of this section in the manner proposed by the commenter.

New Requirements for Construction Completion Dates

Comment 007-33: Several commenters noted that proposed §§ 50.23, 52.77 and 52.79(a)(39) would require a COL application to state the earliest and latest dates for completion of construction. The commenters stated that the requirement to specify a construction completion date should only be applicable to construction permits, and not to combined licenses. The commenters recommend that NRC delete the requirement to specify the earliest and latest dates for completion of construction for a combined license.

The commenters noted that there currently is no requirement for a COL to specify the completion dates for construction. The commenters also noted that when the NRC amended its regulations in 1992 to reflect provisions of the Energy Policy Act of 1992, it specifically removed the provision that would have required a COL applicant to state the earliest and latest dates for completion of construction. [57 FR 60975, December 23, 1992] The commenters noted that the basis for removing this requirement was that it was "no longer required under the legislation." [Id., 60976]

The commenters stated that, in particular, Section 185.a of the Atomic Energy Act requires that a construction permit state the earliest and latest dates for completion of construction. The commenters noted that in contrast, Section 185.b, which addresses a combined license, does not require a COL to specify a construction completion date, nor does it specifically impose the requirements of Section 185.a.

The commenters stated that the Supplementary Information for the proposed rule does not explain why the NRC has changed its view of the requirements in Section 185, other than simply to suggest that the NRC now believes the construction permit provisions in Section 185.a are applicable to a combined license. The commenters asserted that, absent any valid basis for changing its view of the Energy Policy Act of 1992, the NRC should not impose this unnecessary and inappropriate requirement.

The commenters stated that the requirement to specify a construction completion date represents an undue administrative burden with no useful purpose, and the requirement should not be extended beyond the explicit language in Section 185.a (i.e., it should not be extended beyond construction permits). The commenters noted that the experience for Part 50 plants demonstrates that the costs of such a requirement can be substantial. The commenters noted as examples that these costs may include the costs of preparation of requests to extend the completion dates when construction was delayed, the costs of NRC review of such request, and in some cases the cost of expensive hearings on the extension requests. Furthermore, the commenters noted that the NRC routinely granted timely extension requests, without addressing any safety issues and therefore there was no useful purpose served by extension requests or the requirement to specify a construction completion date.

The commenters also noted that the industry does not object to informing the NRC of its expected construction schedules. The commenters understand that the NRC needs such information to plan its construction-related inspections. The commenters stated their expectation that COL applicants will provide construction schedule information to NRC, which is documented in NUREG-1789, Part 52 Construction Inspection Program Framework Document, and most recently in an April 4, 2006, NEI letter to NRC identifying “lessons learned” from the joint industry-NRC ITAAC Demonstration Project.”

NRC Response: The Commission agrees with the commenters that the combined license application need not specify the earliest and latest date for completion of construction, in light of the amendment to Section 185 of the AEA that was made by the Energy Policy Act of 1992. By adding a new Section 185.b., the Commission believes that Congress intended that Section 185.b supersede Section 185.a, so that the Section 185.a requirements for “stand-alone” construction permits, such as the need to specify the earliest and latest date for completion of construction, do not apply to the construction permit portion of a combined license under Section 185.b. Furthermore, by amending only Sections 185 and 189 to specifically address combined licenses, the Commission believes that Congress did not intend to repeal by implication AEA requirements for operating licenses with respect to the operating license portion of a combined license. This is supported by the Report of the Senate Committee on Energy and Natural Resources:

This Section [9101] redesignates Section 185 of the existing Atomic Energy Act as subsection a. and adds a new subsection b. Subsection a. will continue to govern the issuance of construction permits and operating licenses following completion of plants initially granted a construction permit under the old “two-step” licensing process. The new subsection b. will govern the issuance of a combined construction and operating license and the commencement of operation under a combined license.

S. Rep. No. 102-72, 102nd Cong, 1st Sess., p. 292 (1991). Accordingly, the final rule removes the requirements from §§ 50.33(h), 52.77, and 52.79(a)(39) that the combined license application specify the earliest and latest date for completion of construction.

Provisions Recognizing that ITAAC May Be Performed Either in the Plant or Elsewhere Should be Expanded

Comment 007-67: Several commenters pointed out that proposed § 52.47(b)(4) provides that ITAAC related to verifying compliance with interface requirements may be performed “either in the plant or elsewhere.” The commenters recommended also adding the language “either in the plant or elsewhere” to §§ 52.47(b)(2) and 52.80(b) of the final rule.

NRC Response: The NRC disagrees with this comment. Inclusion of the statement “either in the plant or elsewhere” in the rule language is not necessary and the phrase has been deleted from the final rule language. The NRC recognizes that some testing, i.e. type tests, will be performed outside of the plant and these tests will be identified in the ITA column of the ITAAC tables. Also, tests and inspections may be performed at the locations where the components are fabricated. The tests and inspections that need to be performed under as-built conditions should be identified in the ITAAC or supporting documentation.

Contrary to the Proposed Rule, Not All ESP Conditions and Certification Requirements Can Be Completed Prior to Issuance of the COL

Comment 007-52: Several commenters noted that proposed 10 CFR 52.79(b)(3) and § 52.79(d)(3) would require that the FSAR demonstrate that all ESP conditions and certification requirements will be satisfied by the date of issuance of the COL. The commenters stated that it may not be possible to complete all ESP conditions prior to issuance of the COL. The commenters noted as an example that there may be ESP conditions applicable to improvement of subsurface conditions that must be implemented under an approved quality assurance program (i.e., after the COL is issued). The commenters also noted that similarly, it may not be possible to complete all design certification requirements prior to issuance of the COL. The commenters noted as a final example that some of the COL action items specified in the DCD cannot be implemented until construction or initial testing. The commenters recommended that the proposed rule should therefore be modified to account for these possibilities. The commenters recommended that §§ 52.79(b)(3) and (d)(3) be modified to add this phrase to the end, “or the final safety analysis report must include provisions to implement those conditions that cannot be implemented until after the license is issued.”

NRC Response: The NRC agrees in part with the commenters. The NRC agrees that it may not be possible to complete all ESP terms and conditions prior to issuance of the COL and that a similar situation exists for design certifications. Also, although not mentioned by the commenter, the same is true for manufacturing licenses. Therefore, the NRC is making changes in the final rule to several sections. The NRC is revising §§ 52.79(b)(3) and 52.79(d)(3), which were mentioned by the commenters. The NRC is also revising §§ 52.24 (b) and 52.79(e)(3), which contain similar language but were not mentioned by the commenters. However, the NRC is not adopting the commenters’ suggested rule language which would have allowed applicants to address ESP terms and conditions in the COL FSAR. Instead, the NRC is adding language that would require that any terms or conditions of the early site permit that

could not be met by the time of issuance of the combined license be set forth as terms or conditions of the combined license. The NRC believes that any issue that was important enough to be included as condition of the ESP warrants being included as a condition of the COL if it cannot be met prior to issuance of the COL.

Clarification of the Section 50.59 Change Process for COLs

Comment 007-64: Several commenters noted that proposed 10 CFR§ 50.59(b) and 52.98 would make the change process in § 50.59 applicable to holders of COLs. The commenters also noted that under the existing provisions in Section 50.59(c), certain types of changes require a license amendment. The commenters agree that § 50.59 should be applicable to COL holders as soon as the COL is issued. However, the commenters stated that during the period of construction, they believe that a clarification of the 50.59 process is warranted.

The commenters noted that language in existing § 50.59 guidance in NEI 96-07, Guidelines for 10 CFR 50.59 Implementation, which has been accepted by the NRC in Regulatory Guide 1.187, Section 4.5, discusses when an activity is considered “implemented.” The commenters stated that many times during construction, minor changes are needed or minor nonconformances arise that are acceptable as-is from a safety perspective. The commenters suggested that for those changes needing NRC approval under § 50.59, it should be acceptable to make the change at the risk of the licensee, document and control the change as an issue needing further approval, and then confirm the acceptability of the change after the fact to allow construction activities to proceed pending NRC approval of a license amendment. The commenters recommended that this should be permitted for any changes to structures, systems, or components that have not yet been placed in service. The commenters noted that such a process would be consistent with the existing guidance in NEI 96-07 that is referenced above.

NRC Response: The NRC generally agrees that it would be appropriate to apply the guidance outlined in NEI 96-07 and accepted in NRC Regulatory Guide 1.187 regarding when an activity is “implemented” to COLs during construction. The NRC does not believe, however, that any change to the proposed rule language or statements of consideration is necessary.

Support for Conforming Changes and Other Beneficial Proposals

Comment 007-69: Several commenters suggested one additional change to Part 52 that it and its constituents consider necessary to ensure that the regulations are consistent and conform to the Energy Policy Act of 2005 and previous rulemakings.

The commenters recommended that the NRC amend existing § 52.83 to change the reference from § 52.99 to § 52.103(g) as to when the requirements applicable to operating licenses apply. The commenters stated that this would be a correction, and is not intended to be a substantive change. The commenters recommended that this same change should be made to clarify that a Part 52 COL 40-year license term begins at the time the § 52.103(g) finding is made (rather than the § 52.99 finding). The commenters noted that this would also be consistent with the duration of a combined license in the Energy Policy Act of 2005, Section 621. The commenters believe that the proposed rule adequately addresses this issue.

The commenters also recommended that the NRC amend existing § 52.85 to correct the reference to Part 2, Subpart G, hearing requirements. The commenters noted that this paragraph should have been changed in the 2004 rulemaking that amended 10 CFR Part 2. The commenters noted that the paragraph could simply reference Part 2 as the governing regulation for hearing procedures. The commenters believe that the proposed rule adequately addresses this issue.

NRC Response: No response necessary.

Beneficial Changes Proposed for Part 52

Comment 007-77: Several commenters stated that the industry considers the changes in the NOPR in § 52.79(b), (c), (d), and (e), regarding contents of FSARs; in §§ 52.80(b) and 52.97(a)(2), regarding provisions for completion of ITAAC at the COL stage; in § 52.85, regarding administrative review of applications and hearings; in § 52.98, regarding finality of combined license and information requests; in § 52.103, regarding ITAAC hearing and finding process; and in § 52.104, regarding 40-year duration of combined license, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

Comment 011-2: A commenter noted that in § 52.79(b) on page 12900 of the *Federal Register* notice, the paragraph starts “If the application for a safety analysis report...” The commenter argued that “[Applicants] don’t apply for an SAR.” The commenter suggested that it should read either “If the application...” or “If the applicant’s safety analysis report...”

NRC Response: This was an inadvertent error in terminology in § 52.79(b). In the final rule, the NRC has corrected the paragraph to read, "If the combined license application references an early site permit, then the following requirements apply."

Comment 011-5: A commenter noted that in 10 CFR 52.79(b)(3) there is a requirement for COL applicants referencing an ESP to demonstrate that all ESP terms and conditions associated with the FSAR are met. The commenters stated that there doesn’t appear to be an equivalent requirement for environmental terms and conditions. The commenter asked if there should be such a requirement listed in the final rule. [See discussion on § 52.79(b)(3) in Section C.6.f of the NOPR Supplementary Information, pages 12,793 and 12,901.]

NRC Response: The NRC agrees that there should be requirements that a COL applicant referencing an ESP demonstrate that all ESP terms and conditions are met, including environmental terms and conditions. The NRC has added a requirement for COL applicants to address ESP environmental conditions in § 51.50(c)(1) in the final rule.

Allow COL Applicants to Describe Existing Part 50 Operational Programs in a COL Application

Comment 013-6: A commenter recommended that NRC should eliminate ambiguities between Part 50 substantive safety requirements and Part 52 licensing processes. The commenter suggested that a COL applicant should be able to credit existing operational programs that support approval of the COL without ITAAC for such operational programs. The commenter

supports the NRC proposed language to allow COL applicants to describe existing (Part 50) operational programs in a COL application (proposed 10 CFR § 52.79), thereby eliminating the need for duplicative information submittals and NRC reviews.

NRC Response: No response necessary.

Scope of COL Hearings

Comment 013-8: A commenter recommended that the NRC should clearly specify what items are properly included in the scope of COL hearings by placing proper limits on issues resolved in ESP proceedings to eliminate redundant litigation of ESP siting issues in COL or other future licensing proceedings involving a referenced ESP. [See also excerpt 007-8 in Section 5.3.2 of Comment Summaries.]

NRC Response: The NRC agrees that it is important to clarify what items are properly included in the scope of COL hearings in the case where the COL applicant is referencing an ESP. The NRC has made changes to §§ 52.39 and 51.105 in the final rule to address this issue.

Procedures and Schedules for Completion of Pre-operational Hearings

Comment 013-9: A commenter recommended that the NRC carefully control the procedures and schedule for completion of any pre-operational hearing contemplated by 10 CFR § 52.103. The commenter notes that the current framework in Part 52 establishes a compressed schedule (180 days to render a decision from the notice of intended operation) and creates the risk of delaying fuel load and plant startup.

NRC Response: The NRC agrees that NRC must carefully control the hearing procedures and schedule for completion of any hearings associated with the finding under § 52.103(g), as well as ensuring timely determinations that may be needed under § 52.103(c). Several provisions in §§ 52.99 and 52.103 of the final rule were added to support: (i) the conduct of fair, efficacious and timely hearings associated with the finding under § 52.103(g), as well as (ii) timely determinations under § 52.103(c).

NRC Licensing Board Decision Timeframes

Comments 003-11: Several commenters recommended that NRC Licensing Boards should be directed to issue a decision in the 10 CFR § 52.103 hearing within 30 days of the close of that proceeding. The commenters suggested that Licensing Boards would be allowed to deviate from those time limits only with the prior approval of the Commission.

NRC Response: The NRC disagrees with the commenters. The NRC believes, in light of the lack of any NRC experience in the conduct of § 52.103(g) hearings, as well as the lengthy period of time before there will be an opportunity to request a § 52.103(g) hearing, that it is premature to establish in this rulemaking a binding requirement by rulemaking that the presiding officer issue a decision in any § 52.103(g) hearing within 30 days of the closing of the record in the proceeding.

COL Referencing Use of a Manufactured Reactor

Comment 005-23: A commenter noted that on page 12797 of the NOPR, there is a discussion on the proposed requirements in § 52.79(e) for a COL application referencing a “manufactured reactor.” The commenter stated that it appears the reference here should be to a manufacturing license (ML).” The commenter continued, stating that the discussion of siting information in that section is confusing. The commenter recommended that the section should say that the COL application must provide information sufficient to demonstrate that the site characteristics for the site where the manufactured reactor is to be installed are bounded by the site parameters assumed in the license, rather than “the site parameters for the manufactured reactor are bounded by the site” where the reactor will be installed.

NRC Response: The Commission disagrees with the commenter that § 52.79 should refer to a combined license application referencing a manufacturing license, as opposed to the manufactured reactor. A nuclear power plant to be constructed and operated under a combined license would utilize a nuclear reactor - i.e., a physical facility,” rather than an intangible manufacturing license. Moreover, the combined license would not authorize any “manufacturing” under a referenced manufacturing license; all manufacturing of the reactor would be completed before the manufactured reactor was shipped off-site. Accordingly, it is correct to require the combined license application to reference the use of the manufactured reactor, rather than manufacturing license under which the reactor had been manufactured.

The Commission agrees with the commenter that the SOC discussion (71 FR at 12797, second column) is confusing with respect to the siting information that must be provided in a combined license application referencing the use of a manufactured reactor. The SOC and language of proposed § 52.79(e)(1) should have referred to “site characteristics,” rather than, “site.” Moreover, the Commission also notes that § 52.79(e)(1) does not follow the analogous language in 52.79(d)(1). The Commission has addressed this problem in the final Part 52 rule by conforming the language of both paragraphs.

5.3.5 Subpart E - Design Approvals

New Requirement for Design Approvals to Address Emergency Facilities

Comment 007-34: Several commenters noted that proposed 10 CFR 52.137(a)(22) would require that an applicant for a standard design approval include design information on coping with emergencies. The commenters stated that the proposed rule makes no reference to this change, and the purpose and intent of this provision is unclear. The commenters recommend that the NRC delete proposed § 52.137(a)(22).

The commenters asserted that this requirement, taken literally, cannot be satisfied. The commenters stated that the standard design approval applicant will not be responsible for certain emergency planning design features, including the Emergency Operations Facility and other offsite emergency design features (such as sirens). The commenters noted that such design features will be the responsibility of the COL applicant.

The commenters also noted that the same provision is not included in the scope of proposed requirements for a design certification. The commenters stated that it is unclear why an

application for design approval should be subject to greater requirements than an applicant for design certification.

NRC Response: The NRC disagrees with this comment. The requirement to address design features that affect plans for coping with emergencies in the operation of the reactor facility is not a new requirement. This requirement has existed in the former Appendix O to Part 52 (see the last sentence of item #3) for decades and has been adequately addressed in previous final design approval applications. The proposed rule did not discuss this requirement because it was in the former rule. Furthermore, the commenters are misinterpreting this requirement. It does not apply to offsite emergency design features, i.e., sirens.

Elimination of the Option of Renewing a Standard Design Approval

Comment 007-47: Several commenters noted that proposed § 52.147 would prohibit renewal of standard design approvals. The commenters stated that the Supplementary Information for the proposed rule provides no explanation or basis for the prohibition on renewal of a standard design approval. The commenters asserted that a design approval should be subject to renewal, just as a design certification, ESP, and COL are subject to renewal. The commenters stated that there is no reason to prohibit renewals of design approvals.

NRC Response: The NRC does not agree with this comment. The original Appendix O to Part 52 did not contain a process for renewing design approvals and most of the design approvals issued under Appendix O were for a 5-year duration. In this rulemaking, the Commission has tripled the duration for a design approval and believes that renewals will not be necessary. Also, as stated before, the Commission favors the use of the design certification process, which includes a process for renewals.

Beneficial Changes Proposed for Part 52

Comment 007-78: Several commenters stated that the industry considers the changes in the NOPR in § 52.147, regarding the 15-year duration of a standard design approval, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.3.6 Subpart F - Manufacturing Licenses

Limitations on Manufacturing Licenses - number of reactors manufactured, term of license, initiation of manufacture in 3-year period before expiration

Comment 007-48: Several commenters noted that proposed § 52.167(b)(3) would limit the number of reactors that may be manufactured under a manufacturing license to that number of reactors whose start of manufacture could practically begin within a 10-year period. The commenters also noted that proposed § 52.173 would allow the manufacturing license to be valid for not less than 5, nor more than 15 years from the date of issuance, and would permit renewal. However, the commenters went on to note that proposed §§ 52.173 and 52.177(c) would impose the restriction that a manufacturer may not initiate manufacture of a reactor less

than 3 years before the expiration of the license, even though a timely application for renewal has been filed with the NRC.

The commenters stated that the Supplementary Information for the proposed rule provides no justification for establishing these requirements and limitations, other than stating that the 3-year period provides “a reasonable period for completing the manufacture of a nuclear power reactor, based in large part upon public statements by various reactor vendors that they have set goals for constructing complete nuclear power plants onsite within 3 years.” In the commenters’ view, there is no practical reason to impose such restrictions. The commenters stated that if a plant design that is the subject of a manufacturing license remains technically viable to purchasers, the NRC should not unduly restrict the market by removing the vendor’s capability to meet the needs of its customers. Further, the commenters stated that there appears to be no basis related to safety for restricting the use of the manufacturing license as long as the manufacturing is conducted in accordance with the terms of the license.

NRC Response: The Commission, upon further consideration, has decided to remove the requirement from proposed § 52.167(b)(3) with respect to the number of nuclear power reactors authorized to be manufactured. The Commission agrees that if a manufactured nuclear power reactor continues to be commercially viable throughout the term of the manufacturing license, there should be no reason why the Commission should restrict in the manufacturing license the number of reactors that can be manufactured under the license. Moreover, including such a limit may actually serve as a disincentive for the manufacturer to improve the efficiency and productivity of manufacturing, inasmuch as the license limits the number of reactors that may be manufactured. Accordingly, the Commission has removed the requirement in § 52.167(b)(3) that the manufacturing license specify the number of reactors authorized to be manufactured.

The Commission established the five (5) and fifteen (15) year minimum and maximum term of license to be generally consistent with the term of a standard design certification. The Commission believes that the term of a design certification is an appropriate starting point because both regulatory approaches involve NRC approval of the final design of a reactor and the period in which the approved design may be utilized.

The Commission disagrees with the commenter’s proposal that the three-year restriction on commencement of manufacture of a reactor in both §§ 52.173 and 52.177(c) should not be adopted in the final rule. As stated in the SOC, 71 FR at 12801, the Commission established the 3- year deadline for timely submission of an application for renewal of the manufacturing license, consistent with the Timely Renewal Doctrine of the APA. The Commission clarifies that the 3-year deadline for filing of a timely renewal application is intended to ensure that the NRC completes action on the renewal application before the term of the license expires so that recourse to the Timely Renewal Doctrine is unnecessary. This is consistent with the Commission’s rationale in 1989 when it established the period for timely filing of a renewed operating license for nuclear power plants under Part 54 of this chapter. The Commission continues to believe that public confidence in the regulatory process is maintained by establishing a renewal application deadline in this fashion. Accordingly, the Commission declines to adopt the commenter’s suggested change to § 52.173, and no change to the final rule has been made in this regard as the result of the comment.

The Commission also disagrees with the commenter’s proposal that § 52.173 should be modified to allow the manufacture of new reactors to commence after expiration of the

manufacturing license, so long as a timely application for renewal has been filed. The Commission does not believe that commencement of manufacture of a new reactor (as opposed to completion of a reactor whose manufacture has already started at the time of filing for renewal) is an activity of a “continuing nature” for which the timely renewal provision in the APA applies. 54 FR 64962-63⁵. Moreover, analogous to the “public confidence” rationale described above, the Commission believes that public confidence in the renewal process would be adversely affected if the Commission were to allow the initiation of manufacture of a new reactor after the expiration of the manufacturing license. Accordingly, the Commission declines to adopt the commenter’s suggested change to § 52.173, and no change to the final rule has been made in this regard as the result of the comment.

Comment 005-28: The commenter stated that on p. 12807, in the discussion of the specification of “earliest and latest” dates for COLs and MLs, it is not clear why these are required for an ML. Since the ML is issued for a fixed term, the date of issue and date of expiration would appear to establish those criteria. For a COL, the NRC does not state if it is possible to modify the “latest date” for completion of construction. If it is not possible to do so, this requirement would appear to be meaningless, since it would encourage a COL applicant to specify a date sufficiently far in the future to preclude the possibility of forfeiting the license because of unforeseen delays.

NRC Response: The Commission agrees with the commenter. As discussed in the SOC for the proposed rule (71 FR at 12801, third column), the Commission is not specifying an earliest and latest date for completion of manufacture. The SOC discussion at p.12807 is incorrect, inasmuch as proposed § 50.55a(a) and (b) did not specify that a manufacturing license is subject to the condition that the earliest and latest date of manufacture be specified. This discussion has been deleted from the SOC for the final rule.

Changes to Manufacturing License

Comments 007-49 and 005-25: Several commenters noted that proposed § 52.171(b)(1) would not allow the holder of a manufacturing license to make changes, except by means of a license amendment. The commenters also noted that the Supplementary Information for the proposed rule states that the “NRC proposes to provide a greater degree of finality to a manufacturing license,” and that “one of the key reasons for licensing manufactured reactors is to enhance standardization.” The commenters continued to note that the NRC also suggests that allowing changes could result in losing the advantages of a manufactured reactor if each one is treated as a “one-off” custom product.

The commenters stated that the need for NRC approval of every change to a manufacturing license that may be identified is not justified. The commenters asserted that, on the contrary, a manufacturer can maintain the concept of a standard design when making relatively minor

⁵The Commission notes that the final License Renewal Rule established a 5-year period for timely submission of a renewed operating license application. However, as indicated in the SOC for the final rule, the 5-year period was established to be consistent with the Commission’s decommissioning rules which require submission of decommissioning plans and related financial assurance information about 5 years before expiration of the operating license. See 56 FR at 64962 (third column).

changes in procurement, manufacturing, and quality assurance processes, as allowed by or consistent with the 10 CFR 50.59 change process. The commenters suggested that the manufacturer would periodically report these changes to the NRC and the change processes would be subject to NRC oversight.

In this regard, the commenters stated that there is no greater need for standardization of reactors fabricated under a manufacturing license versus reactors constructed under a design certification. The commenters noted that, as provided in 10 CFR 52.63(b)(2) and Section VIII.B.5 of the design certification rules, a COL holder or applicant may depart from a design certification using a § 50.59-like process. The commenters asserted that this same flexibility should be afforded to the holder of a manufacturing license.

One of the commenters also noted, given experience to date in which changes to certified designs are being requested by prospective COL applicants, it is not clear why the NRC believes that the situation would be any different for a “manufactured” reactor. Moreover, the commenter stated that by “freezing” the design under a manufacturing license for up to 15 years, the NRC stifles innovation and improvements that could improve safety and reliability. The commenter noted that while enhancement of standardization is a worthy goal, there are circumstances in which advancement of technology and improvement of safety demand departures from a standard approach. The commenter stated that this provision of the NRC’s rules ignores that fact.

The commenters stated that it simply is not realistic to expect zero changes in a reactor design over a 15-year period. The commenters noted that, due to factors such as obsolescence of components and changes by component suppliers, minor changes should be expected. The commenters stated that it would pose an undue burden on the holder of the manufacturing licensee and the NRC to require such minor changes to be subject to prior NRC review and approval.

NRC Response: The Commission does not agree with the commenters that the design of a manufactured reactor should be subject to less-stringent change provisions (e.g., the use of 50.59 for all portions of the design to be manufactured) than a standard design certification. The commenters have not demonstrated that there are special or unique aspects of manufacturing, as compared with construction of nuclear power plant based upon a referenced standard design certification, that would weigh against maintaining the high degree of design standardization achieved by design certification. Hence, the Commission believes that - similar to requirement for design certification changes to be accomplished by rulemaking - changes to the approved design in a manufacturing license should be accomplished in all cases through license amendments.

One commenter correctly noted that changes in such manufacturing matters as procurement, manufacturing processes, or quality assurance are not subject to the proposed § 52.171(b)(1) change restriction, because these matters do not constitute changes to the approved design of the reactor to be manufactured. Such matters may be changed in accordance with applicable change process and restrictions already established in the Commission’s regulations (e.g., § 50.59, 50.54(a)), and may not require license amendments.

The Commission does not agree with the commenter who argued that a requirement for license amendment to change the approved design in a manufacturing license would stifle innovation

and safety improvements. It is unclear why the need to obtain NRC approval via a license amendment would prevent a manufacturing license holder from seeking changes which are innovative or safety-enhancing.

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

The Commission does not agree with one commenter's proposal to allow a holder of a manufacturing license to change the approved design under the § 50.59 change process. The commenter's assertion, that § 52.63(b)(2) and Section VIII.B.5 of the four standard design certification rules approved to date allow a COL holder to depart from a referenced design certification, is misleading. The VIII.B.5 change process applies only to "Tier 2" changes which are not "certified." The § 52.63(b)(2) process provides for plant-specific departures from Tier 2 of the standard design, i.e., the approved design itself is not being changed, and the departures permitted by rule are limited to Tier 2. By contrast, the "Tier 1" portion of the design which is "certified" is subject to the much more stringent change standards in § 52.63(a). As stated in the SOC, the Commission wishes to maintain a high degree of standardization in manufacturing licenses as well.

For these reasons, the Commission declines to adopt the commenters' suggested changes, and no change to the final rule has been made as the result of this comment.

"Economic Risk" is Not an Appropriate Justification for Changes to Regulations on MLs

Comment 005-24: A commenter stated that it is not clear to their organization why the NRC is using "economic risk" arguments as a basis for proposing changes to Appendix M on manufacturing licenses. [See 71 FR 12800] The commenter noted that aside from the fact that the capability of the NRC to anticipate economic impacts to potential applicants is open to question, this has in the past not been a criterion that the NRC has employed to determine the necessity of changes to regulations. The commenter recommended that the NRC limit its considerations for making changes to Part 52 and related regulations to those associated with public health and safety, along with the need to provide clear and unambiguous regulatory requirements. The commenter stated that "economic risk" should be an issue left to industry assessment.

NRC Response: The Commission believes that the commenter misunderstood the Commission's argument in this regard. The Commission was suggesting that the economic incentives and limitations for approval of a final design for manufacture, are the same as those faced by applicants for standard design certifications. Inasmuch as there continues to be

interest in design certification by potential design certification applicants, the Commission believes it is reasonable to conclude that a requirement for a final design in a manufacturing license is neither unreasonable nor economically impracticable.

The Commission disagrees with the commenter's suggestion that the Commission should limit its consideration for Part 52 changes to those associated with public health and safety. The commenter's suggestion ignores the Commission's statutory responsibility to address common defense and security as well as radiological health and safety. More importantly, the commenter's suggestion precludes the Commission from considering and adopting some of the significant changes sought by nuclear power industry stakeholders in the Part 52 rulemaking, which are not based upon radiological health and safety concerns but by considerations of economics, regulatory efficiency, and reduction of unnecessary regulatory burden. One example would be stakeholder suggestions that the Commission modify § 52.79 to allow design certification rules to be amended to incorporate changes resulting in significant improvements in efficiency or economics. See NEI May 30, 2006 comment letter, at p. 20-23; Westinghouse comment letter, at p. 4. If the commenter's position were adopted by the Commission, the Commission would be unable to consider or adopt such changes. Nor would the Commission be able to identify, on its own initiative, potential rulemaking changes - such as the changes proposed for the manufacturing licenses - which reduce unnecessary regulatory burden while maintaining or enhancing public health and safety or common defense and security.

In any event, the commenter did not identify any fundamental problem with the Commission's proposed changes to the manufacturing license requirements in Part 52. Accordingly, no change was made in the final rule as the result of this comment.

Conditions Under Which Manufacturing License Will be Granted

Comment 005-26: A commenter recommended that the NRC should clarify the conditions under which an NIL can be granted. The commenter also asked if manufacturing licenses are only for reactors that are small enough to be built offsite and transported essentially as a single unit to another location for installation, or would it be possible for a manufacturing license to be granted for the manufacturer of a large plant that would be transported to its site in sections or "modules" for installation.

NRC Response: The Commission's concept for a manufacturing license under Subpart F is the same concept that was originally adopted in Appendix M of Part 50, and transferred to Appendix M of Part 52, viz., the license would approve the manufacture of an entire nuclear power reactor to be transported as single unit from the location of manufacture to the ultimate site of the nuclear power plant. This is clearly reflected in the language of §§ 52.151 and 52.153.

The Commission considered adopting a regulatory approach for manufacturing licenses that would allow approval of the manufacture of modules or sections for a single large reactor at a manufacturing location, to be transported to another site where the modules or sections would be "assembled/integrated into a single working nuclear power plant. However, the Commission decided against extending the manufacturing license concept in this rulemaking to such modular or sectional manufacture, for several reasons. First, the concept represents a significant extension beyond the current manufacturing license concept, and constitute a

substantial extension of the concept of “manufacture” for which a manufacturing license is necessary under Section 185 of the AEA. Second, the extension of the NRC’s jurisdiction to the “manufacture” of modules and section, and its policy and legal ramifications, had not been discussed with external stakeholders during the Part 52 rulemaking development process. Although the concept of approving a final design for a manufacturing license was not discussed with external stakeholders during the rulemaking process, the Commission believed that this proposal was a logical extension of the principles underlying Part 52, in particular, early resolution of design issues. By contrast, requiring a license for the “manufacture” of modules or sections of a plant, raises issues regarding the regulatory need for licensing of other activities that could be regarded as “manufacturing,” viz., the fabrication of components. The Commission is not adverse to the commenter’s proposal; it is both the timing of the proposal and the value of greater public interaction with stakeholders that are of Commission concern. If there is interest in developing the concept, the commenter and/or interested stakeholders may submit a petition for rulemaking.

5.3.7 Subpart G - Enforcement

No comments received.

5.3.8 Design Certification Rules

Comment 005-12: The commenter noted that on page 12808, in its discussion of 10 CFR 50.59, the NRC states that when a COL references a DC rule, the change processes for a design control document (DCD) incorporated in that rule are controlled by what is specified in the DC rule. This discussion helps to illuminate a troubling element of Part 52, particularly after a plant begins operation. The NRC has, over the years, evolved a process for making changes in operating plants, as controlled by the appropriate sections in 10 CFR Part 50 (including, but not limited to, 10 CFR 50.59), and associated regulatory guidance. It is possible, however, for plants licensed under Part 52 to be subject to new rules that establish a new, parallel process governing such changes, including (but not limited to) the Tier 1 and Tier 2* requirements in DC rules that are supposed to apply for the life of the plant. In light of the evolution of technology over the period for which these plants are designed to operate (60 years or more) it is not clear why it is necessary to restrict changes in such a fashion. This is another case in which the goal of “standardization” is apparently raised above any other aspect of plant design and operation, including that of safety. The commenter indicated that the policy governing changes in various aspects of plant design and operation (e.g., fuel design criteria included in Tier 2* DC rules) imposes an additional, undue burden on Part 52 licensees where those requirements exceed those imposed on Part 50 licensees. The commenters recommended that, for those aspects of plant design and operation for which Part 50 controls exist, the NRC should employ those controls rather than establish a parallel process in Part 52.

NRC Response: The NRC does not agree with this comment. As stated in § 52.98(c), if the combined license references a certified design, then changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule. This requirement supports the goal of achieving and maintaining the safety benefits of standardization, which both NRC and the nuclear industry support.

Clarification of Severe Accident Change Process for Departures from Tier 2 of Design Control Document

Comment 007-10: Several commenters noted that the proposed rule includes modifications to Section VIII.B.5.c of each of the appendices to Part 52 for design certification. This section of the design certification rule specifies the process for determining whether or not a license amendment is required for a departure from Tier 2 affecting resolution of a severe accident issue. The proposed changes to Section VIII.B.5.c are currently limited to modifying the introductory language to conform to 10 CFR 50.59 terminology (i.e., it would delete references to “unreviewed safety question” and “safety evaluation”).

The commenters stated that clarification is needed in the rule language both for consistency with the terminology in 10 CFR 50.59 and to conform to the Commission’s intent for this section of the rule, as explained in the Statement of Considerations for each of the design certification rulemakings. The commenters quoted the Westinghouse AP1000 final rule, the Commission’s purpose for Section VIII.B.5.c. [See 71 FR @ 4462, 4474, Jan. 27, 2006.]

In addition, the commenters noted that during a public meeting with the NRC on April 18, 2006, the NRC clarified that the change process in Section VIII.B.5 of the design certification rules was not intended to apply to discussions of the probabilistic risk assessment in Tier 2. The commenters believe that this is an important clarification that should be reflected in the design certification rules so that the rule language is not misconstrued.

NRC Response: The NRC does not agree that the rule language in Section VIII.B.5 of the design certification rules (DCRs) needs to be clarified as proposed by NEI. The NRC believes that the SOC for each of the DCRs provides sufficient explanation for this provision. Also, because the rule clearly applies to departures from severe accident design features, rule language is not needed to state that the severe accident change process is not applicable to the probabilistic risk assessment in Tier 2.

5.4 Changes to 10 CFR Part 50

5.4.1 50.1-50.9 General Provisions

No comments received.

5.4.2 50.10-50.13 Requirement of License, Exceptions

Support for Limited Work Authorizations (LWAs)

Comments 004-1, 004-2, 004-3, and 004-26:⁶ The commenters supported the Limited Work Authorizations process that were promulgated by the NRC in the past. The LWA allows for the applicant to conduct certain activities in parallel with the NRC’s licensing process and before issuance of a COL. The commenters emphasized that minimizing licensing time is critical for

⁶Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI’s comments submitted on May 25, 2006. Therefore, all of these commenters are included in each of NEI’s May 25, 2006 comments (comment number 004). For simplicity, these comment numbers are not repeated in this document for each comment.

prospective COL applicants to reduce schedule time and costs. The specific “pre-construction” activities that new plant applicants may need to initiate will be both site-specific and technology-dependent to a certain extent. Additionally, commencement of certain pre-construction activities in parallel with the NRC licensing process will mitigate schedule impacts occasioned by placement of a new nuclear facility on a site with a currently operating reactor.

NRC Response: The Commission is proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. These revisions to the LWA process will contribute to minimizing NRC licensing time, and will allow entities to commence pre-construction activities in parallel with the NRC licensing process.

The NRC should not overstep its jurisdiction under AEA and NEPA.

Comments 004-6 and 004-14: The commenters argued that NRC’s authority is “confined to scrutiny of and protection against hazards of radiation” as found in *New Hampshire v. AEC*, 406 F.2d 170, 175 (1st. Cir 1969), cert. denied, 395 U.S. 962 (1969), see also *Gage v. AEC*, 479 F.2d 1214, 1221 n.19 (D.C. Cir. 1973). They said the Commission lacks the authority to mandate that an applicant take certain actions that are unrelated to radiological considerations.

NRC Response: The NRC agrees with the comment.

NRC should revise regulations regarding construction and LWAs

Comment 007-28: The commenters found that the proposed § 50.10(e)(3) would continue to restrict safety-related construction activities that could be conducted prior to issuance of a COL to the installation of structural foundations, including any necessary subsurface preparation. The commenters proposed that the NRC amend its regulations to specifically allow a COL applicant that references a design certification to conduct any construction activity approved as part of the design certification.

NRC Response: The NRC agrees with the comment. After consideration of the public comments on limited work authorizations (LWAs), the Commission is proposing to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule.

Comments 004-4, 004-6, 004-7, 004-9, 004-10, 004-11, and 004-13: The commenters stated that the definition of “construction” reflected in 10 CFR 50.10(b) is based on the correct interpretation of the NRC’s responsibility under the Atomic Energy Act and is consistent with the agency’s NEPA obligations. The commenters noted that while the license requirement in § 101 of the AEA does not specifically identify “construction” of a utilization facility as an activity requiring a license and § 185 of the Act describes construction permits and COLs, 42 U.S.C. § 2235, it does not prohibit “construction” directly. See *supra*, § I.A. The commenters questioned what constitutes “construction” for which a prior NRC license is required.

NRC Response: The NRC agrees with the comments. The Commission is proposing to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule.

Comments 004-4, 004-6, 004-7, and 004-13: The commenters argued that the restrictions on the “commencement of construction” under § 50.10(c) are at odds with § 50.10(b).

The commenters point out that neither the AEA itself nor any legislative history attempts to define “construction” (or otherwise define the point at which the licensing requirement is triggered) and they cite Carolina Power & Light Co. (Shearon Harris Nuclear Power Plant, Units 1, 2, 3, and 4), CLI-74-22, 7 AEC 939 (1974). The commenters noted that the 10 CFR 50.10(b); 25 FR 8712, September 9, 1960) NRC regulations concluded that “construction” included pouring the foundation for, or the installation of, any portion of the permanent facility on the site. However, the commenters noted that the “newer” regulations state that, notwithstanding the activities permitted under § 50.10(b), no person shall effect “commencement of construction” without a permit.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-14: The commenters stated that the definition of “construction” in 10 CFR 50.10(b) is fully consistent with the requirements in § 185 of the AEA. The pre-licensing, pre-construction elements listed in §§ 50.10(b) and 50.10(e)(1) involve site-preparation and logistical support and, as such, do not involve making or forming devices or equipment capable of using special nuclear material that are prohibited without an NRC construction permit. The intent of Congress in the AEA is clear and unambiguous: “construction” can only mean activities related to assembling devices capable of utilizing special nuclear material. (See New Hampshire, 406 F.2d at 175). Thus, the Commission’s original interpretation of “construction of a utilization facility” referenced in § 50.10(b) is reasonable and entitled to considerable deference. See *Chevron*, 467 U.S. at 844-845; see also, *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference due to agency depends on, among other things, the consistency of the agency’s position).

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission is proposing to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comments 004-4, 004-8, 004-9, and 004-14: The commenters noted that the restrictions on the “commencement of construction” in § 50.10(c) and the prohibitions on pre-licensing activities in § 50.10(e)(1) are unnecessary under NEPA and relevant statutes. The commenters recommended these be deleted in order to align NRC regulations with an evolved understanding of an agency’s role under NEPA case law that post-dates existing § 50.10(c). Further, the commenters argued that in contrast with the reasonable interpretation of “construction” in § 50.10(b), 10 CFR 50.10(c) establishes an inexplicably circular definition of “commencement of construction.” Activities in the definition of “commencement of construction” include activities that are not “construction” under § 50.10(b) and do not require a construction

permit. Logically, however, if activities are not “construction” under § 50.10(b), they should not be “commencement of construction” under § 50.10(c). If an activity does not fall within the definition of construction under § 50.10(b) and does not require a construction permit under § 185 of the AEA, prior NRC approval of that activity should not be necessary under the AEA.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopting substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 007-29: The commenters request that NRC clarify that pre-construction activities include manufacturing of modules. The commenters recommended that § 50.10(b) continue to allow the procurement or manufacture of components of the facility prior to issuance of a CP or COL. The commenters further suggested that the Part 52 final rule should clarify (possibly in the Supplementary Information provided by the Commission) that this exclusion applies to the procurement and manufacturing of Part 52 facility construction modules, and that a CP or COL applicant may procure or manufacture construction modules.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NRC should allow for an accelerated LWA-2 process.

Comments 004-5 and 004-22: The commenters recommended that LWA-2 findings be accelerated based on the applicant submitting a partial environmental analysis, a partial environmental review by the staff, and related findings by the NRC Atomic Safety and Licensing Board focused only on the impacts of specific proposed LWA-2 activities. The commenters alternatively recommended that the Commission could remove the requirement that the presiding officer make environmental findings for LWA-2 activities and authorize the staff to make those findings instead. See *Union of Concerned Scientists v. U.S. Nuclear Regulatory Commission*, 920 F.2d 50, 56 (D.C. Cir. 1990) (“While NEPA clearly mandates that an agency fully consider environmental issues, it does not itself provide for a hearing on those issues.”)

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-22: The commenters stated that issuance of an LWA-2 based on focused environmental findings would be acceptable under NEPA and that the NRC has successfully employed similar processes on prior occasions. The commenters stated that the NRC could separately consider different segments of a proposed project. See *Tennessee Valley Authority (Clinch River Breeder Reactor Plant)*, CLI-82-23, 16 NRC 412, 424 (1982) (noting that separate

consideration of different segments of a project is “well-established”). The NRC could also authorize an individual, sufficiently distinct, portion of an agency plan without awaiting the completion of a comprehensive environmental impact statement so long as the environmental treatment under NEPA of the individual portion is adequate and approval of the individual portion does not commit the agency to approval of other portions of the plan. [See *Kerr-McGee Corp. (West Chicago Rare Earths Facility)*, CLI-82-2, 15 NRC 232, 265 (1982), *aff’d sub nom. City of West Chicago v. NRC*, 701 F.2d 632 (7th Cir. 1983); *Peshlakai v. Duncan*, 476 F. Supp. 1247, 1260 (D.D.C. 1979); *Conservation Law Foundation v. GSA*, 427 F. Supp. 1369, 1374 (D.R.I. 1977).] Further, the NRC is not responsible for ensuring that the applicant has received the appropriate state, local, or federal permits needed to perform LWA activities. See *Public Service Co. of Oklahoma (Black Fox Station, Units 1 & 2)*, LBP-78-26, 8 NRC 102, 123, 129 (1978) (holding that applicants are not required to have every permit in hand before a LWA is granted).

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-25: The commenters stated that with respect to any hearing on LWA-2 issues, the presiding officer may conduct separate hearings and issue separate partial decisions on issues pursuant to NEPA, on general site suitability issues specified by 10 CFR 50.10(e), and on certain limited work authorization issues. *United States Department of Energy et al. (Clinch River Breeder Reactor Plant)*, LBP-83-8, 17 NRC 158, 161 (1983), vacated as moot, ALAB-755, 18 NRC 1337 (1983). Separate LWA and COL hearings are simply separate phases of the same proceeding. *United States Department of Energy et al. (Clinch River Breeder Reactor Plant)*, ALAB-761, 19 NRC 487, 492 (1984). The Commission may therefore appropriately direct the presiding officer, where appropriate (or requested by an applicant), to consider bifurcating, and conducting separately, the COL and LWA-2 portions of a proceeding. Accordingly, the NRC should take the steps necessary to enhance the LWA-2 process.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 007-28: The commenters recommended that NRC regulations be modified to allow the applicant to propose and justify specific site preparation activities in advance of the submittal of its complete licensing documents to the extent that ESP holders or COL applicants seek to conduct LWA-2 activities. This focused request would be subject to an appropriately focused and expedited staff review and a limited hearing, resulting in the issuance of an expedited licensing board decision on the specific LWA-2 activities requested. The applicant would submit a full environmental report, and the staff would issue a full EIS and hold related hearings, on a less accelerated schedule.

NRC Response: After consideration of the public comments on limited work authorizations

(LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NRC should allow pre-construction activities without permits or LWAs

Comments 004-4, 004-8, 004-12, and 004-18: The commenters recommended that NRC modify its regulations to allow applicants to conduct the pre-construction activities contemplated by § 50.10(b) and 50.10(e)(1) without a prior NRC permit or an LWA. NRC approval of pre-construction activities should focus solely on matters pertaining to safety.

The commenters noted that certain activities are permissible even without an exemption to § 50.10(c) or an LWA (e.g., upgrading existing access roads, drilling exploratory borings, clearing trees, etc.). The NRC allows pre-LWA activities to be undertaken by an applicant if those activities would have a “trivial” environmental impact. Kansas City Gas and Electric Co. (Wolf Creek Nuclear Generating Station, Unit No. 1), CLI-77-1, 5 NRC 1, 12 (1977). The decisions on *de minimis* impacts stress that triviality in this context does not mean “zero” impact, but instead means impacts for which it can “safely be said that no conceivable harm would have been done to any of the interests sought to be protected by NEPA should the eventual outcome of the proceeding be a denial of the application.” [Puget Sound Power & Light Co. (Skagit Nuclear Power Project, Units 1 and 2), ALAB-446, 6 NRC 870, 871 (1977); see also, Washington Public Power Supply System (Nuclear Project Nos. 3 and 5), CLI-77-11, 5 NRC 719, 723 (1977).]

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NEPA does not expand NRC's licensing requirements or jurisdiction.

Comments 004-15 and 004-16: The commenters argued that revising the construction and LWA regulations would leave the NRC still fully compliant with its NEPA responsibilities and would not expand NRC licensing requirements. As a procedural statute, NEPA cannot impose licensing or permitting requirements on a private applicant more stringent than those authorized by the safety provisions of the AEA. [Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989).] The commenters stated that the NRC's current regulations that impose substantive licensing requirements and related environmental obligations on activities that do not require a construction permit, are “inconsistent with NEPA's reliance on procedural mechanisms” and the statute's focus on federal actions. The commenters suggested that the NRC may have taken its obligations under NEPA further than necessary (see Hartsville, 5 NRC at 576) in that while the NRC is obligated under NEPA to consider non-radiological environmental impacts from construction and operation as part of its licensing process, NRC may not prohibit (or require prior NRC approval of) activities that do not entail construction under § 50.10(b) and do not require a construction permit under AEA § 185. The commenters acknowledged that indirect or non-radiological impacts of federal actions would still need to be

reviewed in an environmental impact statement when a federal action becomes involved (i.e., when the licensing requirement of the AEA is triggered). The commenters stated that NEPA does not expand the jurisdiction of or mandate action beyond the agency's organic statute [Gage, 479 F.2d at 1221 n.19; Kitchen v. FCC, 464 F.2d 801 (D.C. Cir. 1972)], and further NEPA does not impose requirements more stringent than those contained in the safety provisions of the AEA. [Philadelphia Electric Co. (Limerick Generating Station, Units 1 and 2), ALAB-819, 22 NRC 681, 696 n.10 (1985) citing Public Service Electric & Gas Co. (Hope Creek Generating Station, Units 1 & 2), ALAB-518, 9 NRC 14, 39 (1979); see also, Methow Valley, 490 U.S. at 347 (1989).]

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comments 004-17: The commenters argued that because pre-licensing site preparation activities are undertaken by private, not federal, entities, they do not require a separate NEPA review when taken on their own. Thus, the commenters suggested that if the activity does not require a construction permit, then NEPA does not require the Commission to prohibit the activity pending NRC review and approval. NRC should not require a construction permit for the pre-licensing activities. The commenters cited the Council on Environmental Quality (CEQ) regulations 40 CFR § 1506(b) and *New Jersey v. Long Island Power Authority*, 20 F.3d 284, 293 (1st Cir. 1995). The commenters acknowledged that while the NRC must assess the environmental impacts of its action, including the indirect impacts and impacts of connected, similar, and cumulative actions, the agency's ability to require prior approval or coerce action only extends to those matters for which approval is required by the AEA.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 004-18: The commenters stated that an agency's jurisdiction is limited to that granted by its organic statute. (Gage, 479 F.2d at 1221 n.19; Kitchen, 464 F.2d at 801). The courts have not enjoined private action under NEPA where the activities fell wholly outside the permitting jurisdiction of an agency. [See e.g., *North Carolina v. City of Virginia Beach*, 951 F.2d 596 (4th Cir. 1996) (allowing continued construction by non-federal entity since a federal agency's environmental review of project was binding only on those aspects that were within the jurisdiction of the agency, even if the agency elected to analyze under NEPA those portions of the project that were beyond its control).]

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NEPA Analysis of pre-licensing activities does not constitute segmentation under NEPA.

Comments 004-19 and 004-20: The commenters stated that where a COL applicant seeks to perform pre-licensing activities, there is but a single federal action - the granting or denial of the COL - whose impacts must be considered under NEPA and that this does not constitute segmentation under NEPA as defined in 40 CFR §§ 1508.7, 1508.8, and 1508.25. Thus, even if the NRC considers the private and federal actions together for NEPA purposes, there is no segmentation since the pre-licensing activities are not “connected” to the NRC’s decision on a COL application. The commenters stated that it is neither “unwise” or “irrational” to complete the pre-licensing activities apart from a COL since those activities merely preserve the option of later COL construction. [Webb, 699 F.2d. at 161; South Carolina v. O’Leary, 64 F.3d 892, 899 (4th Cir. 1995).] Since a COL applicant would be undertaking redressible, pre-licensing actions at its own risk and without expenditure of federal funds, there is no chance of those private actions directly influencing the Commission’s decision on whether the COL should be issued. Therefore, there can be no segmentation as there are no “connected actions.”

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Consideration of indirect actions under NEPA are not grounds for requiring additional environmental analyses for licensing activities.

Comments 004-21, 004-23, and 004-24: The commenters stated that while it might be argued that the pre-licensing activities could affect the ultimate NEPA weighing and balancing of environmental considerations or limit consideration of reasonable alternatives and thus the NRC should require additional NEPA analysis for pre-licensing activities, this argument would not provide a basis for the NRC to prohibit purely private action that does not require a construction permit under the AEA. The commenters noted that the pre-licensing and pre-construction impacts would simply be considered during the overall NEPA evaluation of the subsequent federal action. Moreover, even if NEPA could prevent such private action, the applicant’s at-risk activities are remediable and, in all likelihood, would be addressed in the required site redress plan. Likewise, those pre-construction activities would still be subject to applicable stated and local permits and the related review processes.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters’ concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

NRC should not adopt regulations that would limit allowable pre-construction activities.

Comment 007-28: The commenters stated that proposals that would limit allowable pre-construction activities should not be adopted by the NRC. The commenters stated that the proposed rule contains new requirements that place unnecessary new limits and burdens on

COL applicants and ESP holders that wish to obtain Limited Work Authorizations (LWAs) and perform pre-construction site preparation activities. For example, the current rule contemplates that an ESP holder may conduct site preparation activities authorized by § 50.10(e)(1) without specifically listing or restricting the activities that could be performed. Under the current rule, a COL applicant may request separate authorization to conduct the activities listed in § 50.10(e)(1) or § 50.10(e)(3)(i). The commenters found these proposed amendments even more restrictive and without justification. The commenters did not support these proposed changes, and recommended the solution outlined in the NEI May 25 submittal to allow applicants to conduct activities now categorized as LWA-1 activities without prior NRC review or approval of any kind.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

Comment 007-28: The commenters objected to the proposed § 50.10(e) because like the current regulation, it also appears unnecessarily restrictive in that it would continue to require issuance of an FEIS and issuance of Licensing Board findings as a prerequisite to performing LWA-1 site preparation activities. The commenters suggested that these requirements be eliminated. The commenters argued that there is no need for NRC to approve LWA-1 activities because those activities are not safety-related. Moreover, NEPA does not require hearings on environmental issues. The LWA-1 activities would be at the risk of the applicant and, if necessary, would be subject to site redress based upon the environmental findings of the Licensing Board on the application as a whole.

NRC Response: After consideration of the public comments on limited work authorizations (LWAs), the Commission has proposed to adopt substantially revised provisions on LWAs, as described in a supplementary proposed rule published after the March 2006 proposed rule. The commenters' concerns have been largely addressed by these revisions. Accordingly, no further response is necessary to these comments.

5.4.3 50.20-50.23 Classification and Description of Licenses

No comments received.

5.4.4 50.30-50.33(a) Applications for Licenses, Form, Contents (general)

No comments received.

5.4.5 50.34-50.39 Applications for Licenses, Form, Contents (technical), Ineligibility of Certain Applicants

Comment 005-20: The commenter noted that the text in 10 CFR Part 50 refers to historical requirements or historical agency actions and recommends that the language be removed unless there is a valid purpose to the language.

NRC Response: This comment addresses outdated language in the existing rule text. Correcting rule text that does not relate to the Part 52 processes is outside the scope of this rulemaking. Thus, corrections of this type have not been made in this final rule.

Comment 007-53: Commenters recommended that the following sentence in proposed § 50.34 be deleted: “each applicant for a design certification, design approval, combined license, or manufacturing license under Part 52 of this chapter shall demonstrate compliance with the technically relevant portions of the requirements in paragraphs (f)(1) through (3) of this section.” The commenters argued that this provision is inconsistent with the provisions in existing § 52.47(a)(1)(ii) and proposed §§52.47(a)(17), 52.79(a)(17), 52.137(a)(17), and 52.157(e)(12), which state that paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v) are not applicable to such applicants.

NRC Response: The NRC agrees with the commenter in part. The NRC agrees that proposed § 50.34(f) is inconsistent with proposed §§52.47(a)(17), 52.79(a)(17), 52.137(a)(17), and 52.157(e)(12). However, the NRC does not agree that the references to applicants for design certifications, design approvals, combine licenses, or manufacturing licenses should be deleted from § 50.34(f). Rather, the NRC is making changes to § 50.34(f) in the final rule to make it consistent with the requirements in Part 52.

Comments 007-54, 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017: Commenters noted that the proposed §50.36a would require a COL holder to submit an annual report of effluent releases during the construction period. The commenters recommended that the regulation be amended to require the annual reporting only after the 10 CFR 52.103(g) finding and commencement of operation of the plant. The commenters argued that this would make §50.36a consistent with the current Part 50 regulatory scheme, in which the annual reporting requirement is effective only after an operating license is issued.

NRC Response: The NRC agrees that additional changes are needed to § 50.36a to indicate that a COL holder is not required to submit an annual report of effluent releases until after the Commission has made the § 52.103(g) finding. The final rule contains a change to the reporting provision in § 50.36a(a)(2) to address COL holders.

Comments 007-54, 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017: Commenters noted that § 50.36b could be interpreted as authorizing the inclusion of environmental conditions in a COL that are immediately effective, rather than effective after the NRC has issued its 52.103(g) finding. The commenters recommended that to be consistent with the intent of § 50.36b, the section should be revised to provide that the environmental conditions may only be applied to the period after the NRC has issued its 52.103(g) finding.

NRC Response: The NRC disagrees with the commenters recommendation that § 50.36b be revised to provide that environmental conditions may only be applied to the period after the NRC has issued its 52.103(g) finding. The Commission can place environmental terms and conditions on its permits and licenses and this was stated in the proposed rule in §§ 51.50(a), (b), and (c). The proposed rule stated that, in an application for a construction permit, an early site permit, or a combined license, the applicant shall identify “any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter.” The staff has

modified § 50.36b in the final rule to make this applicability clear.

Environmental Conditions Applied to an ESP

Comment 011-1: A commenter stated that the NRC should clarify whether environmental conditions can be placed on an ESP (similar to 50.36b). [See discussion on § 52.24 in Section C.4.d of the NOPR Supplementary Information, page 12,791.]

NRC Response: The Commission has the authority to include environmental terms and conditions in an ESP. Section 50.36b is revised in the final rule to make this clear.

5.4.6 50.40-50.49 Standards for Licenses and Construction Permits

Comments 005-15 and 007-25: The commenters stated that the proposed rule suggests that changes to 10 CFR § 50.46(a)(3) are necessary to ensure that the NRC is “notified of changes to or errors acceptable evaluation models” used in Part 52 licenses, design certifications or standard design approvals. [71 FR 12805] The proposed changes to 10 CFR 50.46(a)(3) would impose the reporting requirements of 10 CFR 50.46 on design certification and standard design approval applicants, during both the application process and following issuance of the design certification rule or standard design approval. However, the commenters found that there is no reason for the NRC to be made aware of changes or errors unless and until a design certification or a standard design approval is referenced in a COL, operating license, or ML application. If the design certification or design approval is never referenced in a license application, no regulatory action is warranted to change or modify the standard design.

Also, the proposed changes to 10 CFR 50.46(a)(3) would create an unnecessary burden on both the NRC and the industry. A COL, operating license, ML applicant referencing a design certification will be required to identify any change to or error in an accepted evaluation model upon submittal of an application that references a design certification or design approval. Therefore, the necessary notification (and remedial action if warranted) will be taken at that time. Requiring the applicant for design certification or design approval to make a similar notification would be redundant and unnecessary.

Finally, for design certifications, the proposed changes to 10 CFR 50.46(a)(3) are inconsistent with the concept that design certification is a rulemaking proceeding rather than a licensing proceeding. The design certification applicant may not be the ultimate vendor of the plant referenced in the license application. If the design certification applicant is not the vendor, the actual vendor (or other entity designated by the license applicant) will need to develop and maintain its own calculations and evaluations to satisfy the requirements in § 50.46. In such a case, any changes or errors by the design certification applicant would not be relevant to the COL, since the design certification applicant’s evaluation would not be the evaluation of record used by the COL applicant.

In this regard, the commenters argued that the proposed change would represent a fundamental shift in the regulatory philosophy behind the reporting requirement in § 50.46, which has always been applicable to licensees and license applicants. Imposing similar requirements on vendors would represent a substantial departure from the existing regulatory provisions, with no real benefit or value. Furthermore, since the licensee and license applicant

will still be required to make such reports, the proposed rule would require reports by two different entities regarding the same error or change, creating the potential for inconsistencies and confusion.

The commenters suggested that there is no reason to impose a reporting requirement on applicants for design certification or design approval while their applications are pending, because proposed § 52.6(a) will require the applicants to provide information to the NRC that is complete and accurate in all material respects. This obligation is broader than the obligation in § 50.46, and will require applicants to update and correct their applications to account for the type of information covered by § 50.46.

NRC Response: The NRC agrees with the commenters statement that the NRC does not need to be aware of changes or errors unless and until a design approval or design certification is referenced. As a result, the amended rule language for § 50.46(a)(3) has been revised to state that the applicant or holder of a design approval or the applicant for a design certification does not need to report the change or error until the design approval or design certification has been referenced in an application. This process is consistent with the new reporting requirements for 10 CFR Part 21. However, the NRC does not agree that the design certification applicant's evaluation would not be the evaluation of record used by the COL applicant referencing the certified design. Therefore, the design certification and design approval applicants need to report any change to or error in an acceptable evaluation model or in the application of such a model to the NRC and any applicant or licensee referencing the design approval or design certification regardless of whether that applicant is the selected vendor for the applicant or licensee that has referenced the design approval or design certification.

Comment 007-55: The commenters note that § 50.45 states that an application for a COL or COL amendment must meet the requirements in 10 CFR§ 50.21 through 50.38 and 50.40 through 50.43, as applicable. The commenters state that the proposed rule would relocate to Part 52 most of the requirements in 10 CFR§ 50.21 through 50.38 and 50.40 through 50.43 for a COL. However, under the proposed rule, § 50.34 is not applicable to COL applicants (except as provided in proposed § 50.45). Therefore, the proposed rule is not consistent in its treatment of COLs.

NRC Response: The NRC does not agree that most of the requirements in 10 CFR 50.21 through 50.43 were relocated to Part 52 in the proposed rule, but does acknowledge that most of § 50.34 was relocated to the contents of application section for each of the licensing processes in Part 52. Therefore, § 50.45 was revised to set forth the standards for review of an application to alter a facility after the Commission makes the finding under § 52.103(g) of this chapter. The standards for issuance of a combined license are set forth in § 52.97.

Comment 007-56: The commenters stated that the proposed changes to 10 CFR 50.49 would make the regulation applicable to COL applicants and holders. Section 50.49(d) would require a license applicant or holder to have an environmental qualification file for electrical equipment important to safety. Currently, such requirements are only applicable to an applicant or holder of an operating license. Similarly, proposed §§ 52.47(a)(11), 52.137(a)(11), and 52.157(e)(6) would require applicants for design certification, design approval, and manufacturing licenses to include the information required by § 50.49(d). The commenters found that at the time of submission of the applications, and during construction or manufacturing under a COL or

manufacturing license, the applicant/licensee may not have identified the specific electrical components to be installed in the plant, and therefore will not be able to establish qualification files for all applicable components. To be consistent with the intent of the existing rule (which is not applicable during construction), the proposed rule should be modified to indicate that the requirement for qualification files applies only at the time of the NRC's 52.103(g) finding. For the same reason, the commenters recommended that applicants for design certification, design approval, and manufacturing licenses should not be required to establish qualification files, since those applicants may not yet have identified the specific electrical equipment (i.e., make and model) to be installed in the plant.

NRC Response: The NRC agrees that applicants may not be able to establish qualification files, but applicants can provide the electric equipment list required by § 50.49(d). Therefore, the requirements in §§ 52.47, 52.137, and 52.157 have been revised to only require a list of the electric equipment that is important to safety. This amended requirement is consistent with the requirement in § 52.79 and the list can be provided at the time of the application. The verification that the electric equipment has been properly qualified will be done with ITAAC.

5.4.7 50.50-50.55, 50.56-50.58 Issuance, Limitations, and Conditions of Licenses and Construction Permits

Comment 005-19: The commenter stated that on p. 12807, in the discussion of 10 CFR 50.54, the NRC refers to “prerequisites to licenses.” Since a COL may reference a DC or ESP, or both, or neither, the commenter asked NRC to clarify the “prerequisites” to which it is referring.

NRC Response: The statement which the commenter refers to reads, “Conditions applicable to Part 52 processes which are either licenses or prerequisites to licenses, and do not address activities analogous to construction for which a construction permit license is required under the AEA, are proposed to be addressed in § 50.54.” It appears that this statement, as well as other statements in this section, do not reflect the actual rule text issued with the proposed rule. In the proposed rule, only combined licenses and operating licenses are addressed in § 50.54. Therefore, this section has been revised in the final rule to reflect the actual changes to the rule language in §§ 50.54 and 50.55.

Comment 006-8: The commenter expressed concern that certain the proposed changes to NRC regulations in the proposed rule would apply provisions that are applicable to licensees to applicants for design certifications, despite the fact that such design certification applicants are not afforded the protections accorded to licensees under the law. This represents a fundamental shift in the nature of design certification and the status of design certification applicants. Such a fundamental shift is inappropriate, is unfair to design certification applicants, and in many instances is not authorized by law.

During discussions leading to the adoption of Part 52, the commenter sought to allow designs to be certified either by license or rule. The commenter was concerned that design certification by rulemaking would not accord the proponent of a certified design the type of protection that would be accorded to a licensee if a design was licensed. In adopting final Part 52 rule, the NRC rejected the commenter's position of allowing certification either by rule or license. The NRC elected to permit design certification only by rulemaking. [54 FR 15375, April 18, 1989] Thus, applicants for certified design approvals did not become “holders” of a certified design,

and the protections afforded to licensees under the Atomic Energy Act and the Administrative Procedure Act were not provided to such applicants. All references to such an applicant for a certified design approval as a “holder” of the design were deleted when the final Part 52 rule was adopted.

The commenter recommends that all provisions in the proposed rule that would apply to applicants for design certification the requirements applicable to NRC licensees should be deleted.

NRC Response: The Commission disagrees with the commenter that the proposed rule’s imposition on the design certification applicant of new regulatory obligations represents a fundamental shift in the nature of design certification which is “inappropriate...and unfair....” The choice of rulemaking versus licensing in design certification ultimately represents the Commission’s choice of the regulatory vehicle for providing its approval of a final reactor design. While it is true that the regulatory vehicle chosen will determine the manner in which regulatory obligations are imposed, the technical, regulatory and policy bases for the regulatory requirements exist regardless of the regulatory vehicle. For example, take the issue of reporting of defects in engineering on a reactor design. The public health and safety need for prompt reporting to the NRC of such defects is the same regardless of whether the reactor design was submitted to the NRC for approval by license, or approval by rulemaking. That is why Section 206 of the Energy Reorganization Act of 1974, as amended, imposes reporting with regard to “any facility or activity which is licensed or otherwise regulated pursuant to the Atomic energy Act of 1954, as amended...(emphasis added).” The Commission rejects as untenable any argument that a rulemaking “imposing” the legal obligation of design certification applicants to report defects represents a “fundamental shift” in the nature of design certification.

The commenter did not identify the protections which are afforded to licensees under the AEA and APA but are not provided to design certification rulemaking applicants. Therefore, it is difficult for the Commission to address the commenter’s concerns. The one matter of which the Commission is aware of a difference between rulemaking versus licensing, is the protection of proprietary information. In a licensing proceeding proprietary information may be protected from disclosure in accordance with the applicable provisions of the Freedom of Information Act (FOIA). FOIA’s protections for proprietary information do not extend to information in a rule, or forming the bases for a rule; such information must ordinarily be disclosed in a rulemaking proceeding. However, this matter was thoroughly considered and addressed in the 1989 Part 52 rulemaking, and nothing in the 2006 proposed rule changes alters the Commission’s prior consideration of this issue with respect to design certification rulemaking. Moreover, although the commenter argues that “some of the proposed changes” are “not authorized by law,” the commenter does not identify the specific changes in the proposed rule falling into this category, which makes it impossible for the Commission to address the commenter’s concern on a specific basis. Nor does the commenter present any argument in support of this assertion or otherwise address the Commission’s discussion in the SOC for the proposed rule in which the Commission identified the statutory bases for the most significant obligations imposed on design certification applicants, namely, Parts 19 and 21.

For these reasons, the Commission has not made any changes to the final rule in response to the commenter’s suggestion.

New Requirements for an Applicant for an ESP or Design Certification to Describe its Quality Assurance (QA) Program

Comment 007-37: The commenters objected to the broad application of Appendix B requirements. As written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program. The commenters recommended that these provisions be revised to clarify that the Appendix B quality assurance program applies only to activities affecting the safety-related functions of the structures, systems, and components, and not to all ESP site activities, design activities, and construction activities. The recommended changes would make these new Part 52 requirements consistent with existing Appendix B, which states, “The pertinent [QA] requirements of this appendix apply to all activities affecting the safety-related functions [of SSCs].”

The commenters stated that the proposed changes to Appendix B could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B. Not all of those criteria are applicable to each of the applicants. For example, Criterion III on design control, Criterion IX on special processes, and some of the other criteria are clearly inapplicable to ESP applicants. Similarly, Criterion IX, Criterion X on inspections, and some of the other criteria would not be applicable to applicants for design certification and design approval. The commenters recommended that the language be modified to clarify that the applicant need only establish and implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant.

NRC Response: The NRC does not agree that, as written, the proposed rule would require all ESP site activities, design activities, and construction activities to be subject to an Appendix B QA program, as opposed to applying only to activities affecting the safety-related functions of the structures, systems, and components. The commenter quoted the following words from the existing language in Appendix B, “The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components,” [emphasis added], as evidence that the existing requirements relate only to safety-related SSCs. These words have not been removed from Appendix B and therefore apply to all of the new Appendix B requirements for ESPs, design certifications, design approvals, and manufacturing licenses. The NRC notes that the requirements in the current versions of §§ 50.34(a)(7) and 50.55(f) applicable to construction permits do not contain qualifiers that the Appendix B QA requirements apply only to activities affecting safety-related SSCs because such a qualifier is unnecessary given the language in Appendix B to Part 50. In creating parallel requirements for the Part 52 licensing and approval processes, the NRC tried to be as consistent as possible with the existing requirements for Part 50 applicants and licensees.

NEI also commented that some of the proposed language regarding QA requirements could be interpreted as requiring applicants for an ESP, design certification, design approval, or a manufacturing license to establish and implement a QA program that addresses each of the 18 criteria in 10 CFR Part 50, Appendix B and noted that not all of those criteria are applicable to each of the applicants.

The NRC does not agree that the proposed rule language regarding QA requirements for an ESP, design certification, design approval, or manufacturing license needs to be modified. Each of the subject provisions (52.17, 52.47, 52.137, and 52.157) states that the description of the quality assurance program must include a discussion of how the applicable requirements of Appendix B will be satisfied [emphasis added]. Therefore, the NRC believes it is clear that it was not the intent to apply the Appendix B requirements too broadly and that the language in the proposed rule is sufficient to indicate that the applicant need only implement the criteria in Appendix B to the extent that those criteria are applicable to the activities being conducted by the applicant. Therefore, no changes have been made to these sections in the final rule.

Note that on July 19, 2006, the commenter (NEI) informed the NRC by e-mail (ML062710327) that it could not recreate the basis for some of the words in its May 30, 2006 recommended language for 52.17(a)(i)(xii) and that, for purposes of dispositioning this comment, the NRC should ignore them.

Comment 007-57: The commenters stated that the proposed rule would make 10 CFR 50.54 applicable to COLs. Currently, § 50.54 applies only to plants in operation, and is not applicable to plants under construction. To be consistent with this regulatory intent, not all of the provisions in § 50.54 should be applicable to COLs during construction. The commenters recommended that the following provisions in § 50.54 should not be applicable to a COL prior to the time of the 52.103(g):

- (1) 50.54(i), (j), (k), (l), (m), which apply to control room operations
- (2) 50.54(i-1), which applies to operator requalification programs
- (3) 50.54(o), which pertains to containment leak rate testing
- (4) 50.54(p), (q), and (t), which pertain to preparing, maintaining, and/or implementing certain plans
- (5) 50.54(w), which establishes insurance requirements
- (6) 50.54(z), which establishes reporting requirements.

NRC Response: The NRC agrees in part with the commenters. The NRC agrees that not all of the provisions in § 50.54 should be applicable to COLs during construction. However, the NRC does not agree that the provisions in paragraphs (o), (p), and (q) should not be applicable during construction. Paragraph (o) basically requires licensees to comply with Appendix J. Although currently, § 50.54(o) is applicable to operating licensees after the license is issued, Appendix J contains preoperational test requirements. Appendix J requires that preoperational testing requirements be implemented upon completion of construction of the primary reactor containment, including installation of all portions of mechanical, fluid, electrical, and instrumentation systems penetrating the primary reactor containment pressure boundary, and prior to any reactor operating period for Option A. Under Option B, preoperational Type A tests must be performed "after the containment has been completed and is ready for operation" (App. J, Option B, Section III.A.) and preoperational Type B and Type C tests must be performed "prior to initial criticality" (App. J, Option B, Section III.B.). Since Appendix J preoperational testing is likely to occur before fuel load, the NRC believes that it is appropriate to apply paragraph (o) from the time the COL is issued.

With regard to paragraphs (p) and (q), these provisions address maintenance of the security plans and the emergency plans, both of which are approved upon issuance of the COL.

Therefore, the NRC believes it is necessary to apply these provisions from the time the COL is issued. With regard to paragraph (q), the NRC has revised the first sentence in the final rule to indicate that the COL holder is not required follow and maintain in effect the emergency plans until after the Commission makes the finding under § 52.103(g).

In addition, the NRC believes that there are additional provisions, not mentioned by the commenters, that should not be applicable during construction, namely, paragraphs (n), (x), and (y). The exclusion of paragraph (n) during construction is consistent with the changes the NRC is making to § 50.45 regarding alterations to the facility. The exclusion of paragraphs (x) and (y) address situations where the licensee must take emergency action that departs from a license condition or technical specification when the action is needed to protect the public health and safety. Such a situation requiring the protection of public health and safety would not arise prior to fuel load.

In addition, the NRC believes paragraphs (r) and (u) do not apply at all to COLs and has revised § 50.54 to so state. Paragraph (r) only applies to research and test reactor facilities and paragraph (u) was only applicable for 60 days after the amendment to § 50.54 that added paragraph (u).

Comment 007-57: The commenters found that for COLs that reference a design certification, § 50.54(h) as currently worded would be inconsistent the backfit protections of § 52.63.

NRC Response: The NRC does not agree that § 50.54(h) is inconsistent with the backfit provisions of § 52.63. Section 50.54(h) states that the license shall be subject to the provisions of the Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. This provision further states that the terms and conditions of the license shall be subject to amendment revision, or modification by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms of the Act. The provision implements Section 183.d of the AEA, and makes it clear that because there is change to the AEA, or the Commission adopts a valid regulation after the issuance of a license, or issues an order to a licensee, the licensee should not assume that the new statutory provision or regulatory requirement does not apply to it, or that it may ignore the order, solely on the basis that these changes occurred after issuance of a license.

With respect to changes to the AEA, the new statutory requirement always control, and a licensee may not avoid compliance with a change to the AEA on the basis that the change was adopted by Congress after issuance of the license. With respect to new or changed regulations, the applicability of the regulation is controlled by the words of the regulation itself, or if there are no such words in the regulation, than it is applicable to all licensees absent more specific regulatory provisions. The finality provisions in Part 52, including Section 52.63, are an example of such specific regulatory provisions. Finally, with respect to orders, the Commission has power to issue an order, but only consistent with its regulations, unless it has a valid basis for "excepting" itself from its own regulations. In summary, Section 50.54(h) is not inconsistent with Section 52.63.

Comment 007-57: The commenters stated that current paragraph 50.54(u) imposes requirements on each nuclear power reactor licensee to submit to the NRC plans for coping with emergencies. The NRC should consider deleting this paragraph, as it is out of date and no

longer applicable to either operating reactors or new reactor applicants.

NRC Response: The NRC agrees that this paragraph is out of date and no longer applicable but deleting it is outside of the scope of this rulemaking, which is only meant to address issues related to Part 52. The NRC is not attempting to “clean up” Part 50 as part of this Part 52 rulemaking.

Comment 007-81: Several commenters stated that they considered changes in the NOPR in § 50.54(i-1), clarifying that operator requalification programs must be in effect within three months after the § 52.103(g) finding, to be beneficial. The commenters also stated that they considered changes in the NOPR in § 50.54(gg), regarding operation at up to 5 percent power notwithstanding Federal Emergency Management Agency identified deficiencies, provided the Commission makes a reasonable assurance finding, to be beneficial. The commenters recommended that the final rule amending Part 52 should include these changes.

NRC Response: No response necessary.

5.4.8 50.55(a) Codes and Standards

Comment 007-51: The commenters stated that the proposed change to § 50.55a(f)(3)(iii)(A) would constitute an inappropriate backfit. The design certifications issued prior to November 22, 1999, were required to utilize the applicable editions of the American Society of Mechanical Engineers (ASME) Code that were in effect and approved by the NRC at the time. Under the provisions in 10 CFR 52.63(a)(1) and § VIII.B.1 of the design certification rules, the NRC is not allowed to change those design certifications, except to assure adequate protection or to bring the designs into compliance with the Commission’s regulations “at the time the certification was issued.” The Commission has not made such a finding, and therefore the backfit contained in the proposed rule is inappropriate and in noncompliance with the Commission’s own regulations.

The commenters also stated that § 50.55a(g)(3) currently requires that the pre-service inspection of components be performed to the construction code to which the component was fabricated. When plants are under construction, the various components are fabricated to a number of editions and addenda to the construction code. It would be a tremendous burden to the industry to perform a pre-service inspection on multiple components to a number of different editions and addenda. It would be practical to choose one construction code edition and addenda as a code of record for the pre-service inspection. The commenters recommended that § 50.55a(g)(3) be revised.

NRC Response: The NRC disagrees with these comments. The proposed rule simply clarified the applicability of 10 CFR 50.55a. Clarifications of applicability and any periodic updates of § 50.55a do not constitute automatic backfits of existing design certification rules (DCRs). As stated in the comment, the applicable ASME Code editions and addenda are specified in the DCRs and any changes to these commitments would be controlled by § 52.63(a)(1).

Comment 007-82: Several commenters stated that the industry considers the changes in the NOPR in § 55.109, § 50.55a, regarding clarification of when the requirements would be applicable to operation under a combined license and that applicable ASME Code editions will

be those in effect 12 months prior to fuel loading, to be beneficial. The commenters recommended that the final rule amending Part 50 should include these changes.

NRC Response: No response necessary.

5.4.9 50.59-50.69 Issuance, Limitations, and Conditions of Licenses and Construction Permits

Comment 007-35: The commenters argued that the Supplementary Information for the proposed rule does not explain or justify requiring a COL holder to implement the maintenance rule prior to fuel load. Further, the requirement in proposed § 50.65(c) to implement the maintenance rule 30 days before fuel load is inconsistent with the requirement in paragraph 50.65(a) that the maintenance rule applies after the NRC has made its 52.103(g) finding.

The commenters noted that in no case has program implementation been required 30 days (or another arbitrary period) prior to a project/licensing milestone, and that doing so for the maintenance rule would provide no discernable regulatory or operational value. Indeed, the NRC provides no justification for it.

The commenters recommended that NRC should not require implementation of the maintenance rule prior to fuel load when not all systems will have been placed in service. Moreover, most of the requirements in the maintenance rule, such as the monitoring and assessment activities in § 50.65(a), are predicated upon an operating plant. That said, it should be emphasized that, regardless of any NRC requirement, the licensee will have implemented its maintenance programs, as well as its quality assurance and configuration control programs, long before fuel load to maintain and control the configuration of SSCs as they are turned over to operations and placed into service.

NRC Response: The NRC agrees with this comment and has deleted the proposed revision to § 50.65(c). The NRC expects that licensees will have the maintenance program operational by the time that initial fuel loading has been authorized.

Comment 007-58: Regarding the proposed changes to 10 CFR 50.61 that would make this section applicable to a COL holder, among other requirements, this section requires a calculation of reference temperature pressurized thermal shock (RT_{PTS}). The commenters noted that the calculation of RT_{PTS} depends upon material properties of the reactor vessel. At the time of issuance of a COL, it is possible that the reactor vessel may not have yet been manufactured, and therefore its material properties may not be sufficiently known for the purposes of calculating RT_{PTS} . Therefore, the proposed rule should be modified to indicate that § 50.61 applies to a COL at the time the NRC makes its 52.103(g) finding.

NRC Response: The NRC does not agree with the commenter's recommendation. The reactor vessel may be purchased prior to issuance of the COL and the calculation of RT_{PTS} can be resolved during the COL review. For those licensees that purchase their reactor vessel after receipt of the COL, the verification of the reference temperature can be performed with an ITAAC. Therefore, the rule language was not changed.

Comment 007-64: Regarding the proposed changes to 10 CFR 50.59(b) and 52.98 that would

make the change process in § 50.59 applicable to holders of COLs, the commenter noted that under the existing provisions in § 50.59(c), certain types of changes require a license amendment. The commenter stated that § 50.59 should be applicable to COL holders as soon as the COL is issued. However, during the period of construction, the commenter stated that a clarification of the 50.59 process is warranted. The commenter cited existing § 50.59 guidance in NEI 96-07, Guidelines for 10 CFR 50.59 Implementation, which has been accepted by the NRC in Regulatory Guide 1.187 § 4.5.

The commenter noted that many times during construction, minor changes are needed or minor nonconformances arise that are acceptable as-is from a safety perspective. For those changes needing NRC approval under § 50.59, it should be acceptable to make the change at the risk of the licensee, document and control the change as an issue needing further approval, and then confirm the acceptability of the change after the fact to allow construction activities to proceed pending NRC approval of a license amendment. This should be permitted for any changes to structures, systems, or components that have not yet been placed in service. Such a process would be consistent with the existing guidance in NEI 96-07 that is quoted above.

NRC Response: The NRC generally agrees that it would be appropriate to apply the guidance outlined in NEI 96-07 and accepted in NRC Regulatory Guide 1.187 regarding when an activity is “implemented” to COLs during construction. The NRC does not believe, however, that any change to the proposed rule language or statements of consideration is necessary.

Comment 007-68: The commenters argued that the language of 10 CFR 50.69, which allows design certification applicants the option of using the categorization methodologies, is vague and confusing. It has been interpreted as precluding design certification applicants from using the alternative categorization methodologies. Thus, for new plants licensed under Part 52, each combined license applicant that chooses to adopt § 50.69 must perform an extensive analyses and make a submittal to the NRC for an exemption from the structure, system, and component categorization process used in certifying the design. The commenters indicated that in the 1999 staff requirements memorandum on SECY-98-300, Options for Risk-informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities, the Commission approved the NRC staff proposal to risk-inform the scope of systems, structures, and components covered by those sections of Part 50 requiring special treatment (e.g., Quality Assurance, Environmental Qualification, Technical Specifications, § 50.59, ASME code, § 50.72, and § 50.73). The commenters argued amending the language of § 50.69 to clarify that design certifications have the option of using § 50.69 would improve regulatory efficiency and reduce the regulatory burden on combined license applicants and on the NRC staff by allowing the design certification applicant to submit the categorization evaluations just once to the NRC instead of numerous times.

Comment 005-16: The commenter stated that in 10 CFR § 50.69(b)(1), the applicability of the risk-informed categorization and treatment process specifically omits applicants for design certification. Although the NRC explained its rationale for this omission in the *Federal Register* notice for the 10 CFR 50.69 rulemaking (see 69 FR 68035), the commenter did not find those arguments persuasive, particularly in view of the fact that the risk-informed categorization and treatment process is permitted in applications for standard design approval, for which the technical requirements are essentially the same as for design certification.

One of the reasons provided for omitting design certification applicants from applying the 10 CFR 50.69 process was that “the industry has not expressed any interest in submitting a design certification using the principles of § 50.69.” However, when the proposed rule for § 50.69 was published, there was no provision for including design certification applicants, and the NRC did not request comments as to whether such a provision should be included. Thus, the industry was never given an adequate chance to express its interest in such a provision. Consequently, NEI now expresses the industry’s interest in including design certification applicants in the “applicability and scope” section of 10 CFR 50.69.

The commenter recommended that 10 CFR 50.69(b)(1) be amended, and noted that the applicability of § 50.69 requirements to design certification applicants would be defined by the current 10 CFR 50.69(b)(4).

NRC Response: The NRC did not propose any revisions to § 50.69 in this rulemaking and does not agree that § 50.69 should be applicable to design certification applicants. It is important to remember that § 50.69 is a voluntary regulation and COL applicant's who choose to adopt that requirement must first classify their equipment into safety-related and non-safety related categories. Then they can reclassify into the four categories identified in § 50.69. If design certification rules were issued under § 50.69, the COL applicants referencing that certified design would have to adopt the four category approach and lose the voluntary option of § 50.69. Whereas, if design certification applicants do not use § 50.69, then they would all do the mandatory part of the component categorization (safety-related and non-safety related) and subsequently the referencing COLs could voluntarily choose to convert to the four categories of equipment. Furthermore, it is not apparent that sufficient information would be available at the design certification stage to meet the requirements of § 50.69.

5.4.10 50.70-50.75 Inspections, Records, Reports, Notifications

Comment 007-36: The commenters noted that the combined license holder is required to submit a decommissioning funding report in its application, explaining how it will fund decommissioning. The annual update during the construction period would serve no purpose and is unnecessary and unduly burdensome. In addition, such a reporting requirement is not imposed on construction permit holders. The licensee should be allowed to adjust the funding certification at the time construction is complete and the plant is ready to begin operation.

The annual update under § 50.75(e)(3) should not be required prior to the date that the NRC makes the § 52.103(g) finding. Once the NRC has issued its § 52.103(g) finding, the licensee will be subject to decommissioning funding requirements, and must submit periodic reports as provided in § 50.75(f)(1). This approach appears to be consistent with the other requirements in 10 CFR 50.75 for establishing decommissioning funding, and also would accomplish the intent of the regulatory scheme established to ensure adequate decommissioning funding upon the end of the operational life of the plant, as discussed in the NOPR.

NRC Response: The commenter is correct that a decommissioning reporting requirement is not imposed on construction permit holders. However, under the current rule, an operating license applicant must submit to the NRC a copy of the financial instrument obtained as part of the certification contained in the applicant's required decommissioning report. Also, the amount of decommissioning funding assurance to be provided must be adjusted annually by an

operating license applicant. The result is that the NRC will have adequate time to evaluate the financial instrument, which must cover adjusted funding amounts. The Commission believes that for combined licenses, a certain amount of time is also necessary prior to the time the plant is ready to begin operation to allow the NRC to confirm that any significant escalation in decommissioning costs is accounted for by the licensee, and to evaluate the financial instrument the applicant is planning to obtain to satisfy decommissioning funding assurance requirements, particularly non-routine financial instruments that could be used with unconventional funding assurance mechanisms. Therefore, the Commission has concluded that updated annual certifications including a copy of the financial instrument to be used are necessary beginning two years prior to the scheduled date for fuel load. Accordingly, the Commission has decided that the final amendment to 10 CFR 50.75 will eliminate the need for an annual update to the required decommissioning report during the entire time prior to the making of the finding under 10 CFR 52.103(g), and instead require only updates two years and one year before the scheduled date for fuel load. The final amendment will also clarify that a copy of the financial instrument to be obtained, i.e., unexecuted, will be required to be part of the certification contained in the updates of the decommissioning reports to be submitted. The final rule retains the requirement in the proposed rule that an updated decommissioning report, containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification and containing as part of the certification a copy of the financial instrument obtained, must be submitted no later than 30 days after the Commission publishes notice in the Federal Register under 10 CFR 52.103(a).

Comment 007-59: The commenters noted that given the other changes in the proposed rule, § 50.72 could now be construed as applying to a COL upon its issuance. Therefore, the proposed rule should be modified to indicate that § 50.72 applies to a COL only after the NRC makes its 52.103(g) finding.

NRC Response: The NRC agrees with the commenter and has include changes to § 50.72 in the final rule to indicate that it is applicable to COLs only after the NRC makes the finding under § 52.103(g).

5.4.11 50.78 US/IAEA Safeguards Agreement

No comments received.

5.4.12 50.80-50.82 Transfers of Licenses - Creditor's Rights - Surrender of Licenses

New Requirements Related to Transfer of an ESP

Comment 007-22: Several commenters noted that proposed 10 CFR 52.28 would specify that an "application to transfer an ESP will be processed under 10 CFR 50.80." Section 50.80(a) would be revised to include permits issued under Part 52 within the scope of the regulations for transfer of licenses. The commenters agree that an ESP should be subject to transfer, and that NRC regulations should include criteria governing the transfer of ESPs. However, the commenters do not believe that all of the requirements in § 50.80 are relevant to such transfers (e.g., requirements on financial qualifications, requirements for technical qualifications). The commenters suggested that the final rule should reflect that such a transfer would be subject to the "applicable" requirements in 10 CFR 50.80. The commenters also noted that, based upon

the December 27, 2005, NRC staff response to the Commission's SRM on the draft proposed rule, the commenters understood that the NRC agrees with the above comment.

NRC Response: The NRC agrees that not all of the requirements in § 50.80 are relevant to transfers of an ESP and has made changes to § 50.80 in the final rule to specify which criteria are applicable to transfer of an ESP. Specifically, in the final rule, paragraph 50.80(b)(1)(ii) requires an application for transfer of an ESP to include as much of the information described in §§ 52.16 and 52.17 with respect to the identity and technical qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. This change removes the requirement for the applicant for transfer of an ESP to address financial qualifications since this is not required of an initial ESP applicant. In addition, this change removes, for an ESP transfer, the statement that the Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applications' qualifications to protect against such hazards since an ESP does not authorize the holder to possess radioactive material.

5.4.13 50.90-50.92 Amendment of License or Construction Permit at Request of Holder

No comments received.

5.4.14 50.100-50.103 Revocation, Suspension, Modification, Amendment of Licenses and Construction Permits, Emergency Operations by the Commission

No comments received.

5.4.15 50.109 Backfitting

Comment 007-83: Several commenters stated that the industry considers the changes in the NOPR in § 50.109, regarding applicability of the Backfit Rule, to be beneficial. The commenters recommended that the final rule amending Part 50 should include these changes.

NRC Response: No response necessary.

5.4.16 50.110-50.111 Enforcement

No comments received.

5.4.17 50.120 Training and Qualification of Nuclear Power Plant Personnel

No comments received.

5.4.18 Appendix A - General Design Criteria for Nuclear Power Plants

No comments received.

5.4.19 Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

5.4.20 Appendix C - A Guide for Financial Data and Related Information Required to Establish Financial Qualifications for Facility Construction Permits

No comments received.

5.4.21 Appendix E - Emergency Planning and Preparedness for Production and Utilization Facilities

Comment 007-84: Several commenters stated that they considered the changes in the NOPR in Appendix E to Part 50 Emergency Planning and Preparedness for Production and Utilization Facilities, § IV.f.2.a.ii, regarding conduct of the full participation exercise within two years of fuel load, to be beneficial. Several commenters also regarded the changes to Appendix E to Part 50 Emergency Planning and Preparedness for Production and Utilization Facilities, § IV.f.2.a.iii, regarding coordination of the EP exercise for the new plant with that for the operating unit(s), also to be beneficial. The commenters recommended that the final rule amending Part 50 should include those changes.

NRC Response: No response necessary

5.4.22 Appendix F - Policy Relating to the Siting of Fuel Reprocessing Plants and Related Waste Management Facilities

No comments received.

5.4.23 Appendix G - Fracture Toughness Requirements

No comments received.

5.4.24 Appendix H - Reactor Vessel Material Surveillance Program Requirements

No comments received.

5.4.25 Appendix I - Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet ALARA for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents

No comments received.

5.4.26 Appendix J - Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors

No comments received.

5.4.27 Appendix K - ECCS Evaluation Models

No comments received.

5.4.28 Appendix L - Information Requested by the Attorney General for Antitrust Review of Facility Construction Permits and Initial Operating Licenses

No comments received.

5.4.29 Appendix R - Fire Protection Program for Nuclear Power Facilities Operating Prior to Jan. 1, 1979

No comments received.

5.4.30 Appendix S - Earthquake Engineering Criteria for Nuclear Power Plants

Comment 005-18: The commenter stated that the NRC's approach to revising existing parts of 10 CFR is not internally consistent. For example, the term "design certification" is used in the revised Part 50 (see, e.g., new 10 CFR 50.43), but is not included in the new definitions proposed for 10 CFR 50.2. However, a definition for "design certification" is included separately in the new 10 CFR Part 50, Appendix S. The commenter noted that the definition in new 10 CFR 52.1 is given for "standard design certification or design certification," which is not the same as the terminology in the aforementioned Appendix S.

NRC Response: The NRC disagrees with this comment and has determined that the definition of "design certification" in 10 CFR 52.1 and Appendix S to 10 CFR Part 50 are substantively equivalent. Also, the requirement in 10 CFR 50.43 refers to "design certification under part 52." Therefore, the reader would use the definition of design certification in 10 CFR 52.1.

Application Processing

5.5 Changes to 10 CFR Part 1

No comments received.

5.6 Changes to 10 CFR Part 2 – Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders

Comments 003-9, 003-10, 003-11, and 003-17: Several commenters asked why the model schedule in Appendix B to Part 2 allows the presiding officer an additional 55 days to issue a hearing schedule. The commenters suggested that the initial hearing schedule could be established at the same time that the presiding officer issues a decision ruling on intervention and admission of contentions, i.e., within 140 days after publication of the hearing notice. Several commenters believed that the time interval in the model schedule for the beginning of licensing hearings should be shortened considerably. Under Part 2, Subpart L, hearings on COL applications should begin 175 days after issuance of the safety evaluation report (SER) and NEPA document (e.g., environmental impact statement or EIS). The commenters recommended that the hearings proceed based on the information contained in the draft SER and draft EIS, or alternatively, the hearings should begin more promptly than 175 days after issuance of the final SER and final EIS if no additional contentions on the final documents are admitted.

NRC Response: The 55 day-period provided in the Model Schedule for Appendix L hearings was established for several reasons. Section 2.332(a) requires the presiding officer to set a scheduling order only after consulting with the parties by conference, telephone, mail, or other suitable means. Furthermore, § 2.332(d) provides that, in establishing the schedule, the presiding officer considers the NRC staff's schedule for completion of the safety and environmental evaluations. That schedule may depend upon the contentions admitted, inasmuch as the NRC staff may choose to prioritize its evaluations and issue its evaluations in a phased approach to support timely hearings on those matters. See 69 FR 2208-2209. The Commission also notes that once the order admitting parties and contentions is issued, mandatory disclosures must be made automatically under § 2.336(a); the Commission believes that once parties have had a reasonable period of time to assess the disclosed information, the scheduling of the remainder of the hearing will be better-informed. Certainly, the agency's general - if not always consistent - practice prior to adoption of the 2004 revisions to Part 2 was to establish a schedule for completion of the hearing (e.g., summary disposition, submission of pre-filed direct and rebuttal testimony, and cross-examination plans) only after completion of discovery, and some cases only after issuance of the primary NRC staff documents. Thus, the Commission believes that it is reasonable to provide some time for the NRC staff, as well as other parties, to prepare for a scheduling conference. After completion of the scheduling conference, the Commission believes that, depending upon the nature and complexity of the proceeding, the presiding officer will require some time to prepare the scheduling order. Finally, the Commission notes that the Milestones in Appendix B of Part 2 are intended to be general guidelines, and if circumstances permit or necessitate somewhat reduced time periods, the presiding officer has sufficient flexibility to do so, consistent with § 2.332(b), (c), and (d).

Comments 003-1, 003-6, and 013-2: Several commenters recommended that NRC modify the regulations to provide explicitly for the submittal of phased applications and standardized application sections. Specifically, they said that 10 CFR 2.101 should be revised to clarify to NRC that these approaches are acceptable, and this suggestion particularly applies to resolution of DAC and COL action items. They cited several key benefits. Phased submittals and corresponding phased NRC review of COL applications would facilitate completion of the review of potentially extensive portions of the license applications at an earlier date. This in turn would accelerate the overall license review schedule and would permit earlier commencement of hearings. They suggested that standardized license applications will take less time for review than in the past. The commenters suggested that this approach is likely to give NRC staff greater flexibility in allocating its resources, which should lead to more effective use of NRC resources overall. Additionally, it should enable the NRC to issue its formal approvals earlier than it would otherwise be able to do so, since the early submittals could be removed from the critical path.

The commenters illustrated their point with a hypothetical example in which a COL applicant might file those portions of its application that pertain to environmental and siting issues sooner than those portions that pertain to the plant design, to permit early resolution of those issues. They suggested that such early resolution might support the issuance of a limited work authorization under 10 CFR 50.10(e).

NRC Response: The final rule includes revisions to 10 CFR 2.101, and 10 CFR Part 2, subpart F, to clarify that the existing process for phased submission of applications addressing environmental and siting matters separate from safety matters.

The NRC declines to adopt a more general approach for phased applications. An efficient and effective review process requires that each “phase” of a submitted application be essentially complete and self contained. If the portion of the application submitted is not complete, the NRC’s review is likely to be time consuming and possibly incomplete, which would defeat the underlying purpose of the phased submission. The commenters did not address these concerns, nor did they propose criteria or guidelines for ensuring that the portions of applications which are submitted are complete and self contained. Given the difficulties of the phased submission of partial applications with no constraining requirements, and the additional flexibility provided in the final rule as compared with the proposed rule (e.g., extension of Appendix N in Part 52 to duplicate designs, revisions to § 2.101 and Part 2, subpart F as described above, and revisions to the LWA process in 10 CFR 50.12), the NRC believes that the final Part 52 rule provides a sufficiently broad array of administrative and procedural alternatives to potential applicants.

Comment 003-7: Several commenters believed that the establishment of model milestones or recommended schedules would reduce the time taken for the staff to complete licensing reviews and issue safety and environmental licensing documents. They suggested that the Commission should direct NRC staff to docket applications more quickly and complete key licensing documents (e.g., SER, EIS) by a certain deadline, or explain why it cannot do so. The commenters stated that these efforts will facilitate the earlier initiation and, therefore, completion of licensing hearings, because initiation of hearings is linked to the availability of the licensing documents.

Commenter 003 suggested three timeline requirements for the Commission’s consideration:

(1) Require NRC staff to docket an early site permit (ESP), design certification (DC) and COL application within 30 days after the application is filed with the NRC. (NRC regulations in 10 CFR 2.101(a)(2) treat this 30-day review period as a goal, not a requirement.)

(2) Require NRC staff to complete and issue the draft SER or SER with open items and the draft EIS within 12 months after docketing an ESP or “first of class” COL application. For subsequent standardized COL applications, the turnaround time for the draft licensing documents should be shorter. This period could be even shorter for a COL application that references a certified design or a reference COL application.

(3) Require NRC staff to complete and issue the final SER and the final EIS within four months after issuance of the draft SER and EIS. This period could be even shorter for a COL application that references a DC and/or ESP.

NRC Response: The Commission disagrees with the commenter’s general proposal that the Commission establish Model Milestones or (generic) recommended schedules for the Staff to complete its licensing responsibilities. The Commission considered this in the recent Part 2 rulemaking (69 FR 2182; January 14, 2004) and rejected that approach, and the commenter presented no reason for revisiting the Commission’s earlier conclusion. The Commission believes that these are matters of internal agency management, and are not appropriate subjects for rulemaking. The Commission is considering other approaches for addressing this matter, either through issuance of generic guidance to the Executive Director for operations or through case-specific Commission action. Accordingly, the Commission declines to adopt the

commenter's proposal, and no change to any part of the final Part 52 rulemaking has been made as the result of the comment.

The Commission notes that the commenter's proposed time periods for issuance of draft SER and EIS for either an early site permit or a "first of class" combined license, and for issuance of a final SER and final EIS are likely unachievable. For example, the commenter suggests that the final EIS be issued within 4 months (120 days) after issuance of the draft EIS. Under § 51.73, a minimum 45-day comment period must be provided. This provides 75 days for the NRC staff to assess comments, revise the EIS, provide the EIS to the US Environmental Protection Agency for review, and receive EPA's notification of their approval. It may be possible to achieve the schedule in a combined license proceeding where the application references either a standard design certification rule or an early site permit. However, the Commission has no experience with the time needed for review of a combined license, and regards the uncertainties as sufficiently large that it would be imprudent to establish model milestones by rulemaking at this time.

Comments 003-12: Several commenters suggested that the NRC should amend proposed 10 CFR 2.340(e) to clarify that a licensing board decision authorizing issuance of an ESP is immediately effective. This change could save two months or more on the schedule for pre-construction activities for a facility, without affecting the substance of the NRC's review. A licensing board decision authorizing a COL is already immediately effective under § 2.340(h), and ESP decisions should not be treated more restrictively than COL decisions.

NRC Response: The Commission is making changes to §§ 2.340 which render this comment moot.

Comments 003-11, 003-17, and 013-7: Several commenters believed that the schedule for an initial decision on a COL application should be reduced. These commenters the NRC should shorten many of the time intervals specified under Part 2, as applied to 10 CFR 52.103 hearing activities, to facilitate the earlier initiation and completion of the hearings. The model schedule for hearings on COL applications conducted under Part 2, Subpart L, states that the presiding officer should issue an initial decision within 90 days after the end of the hearing and the close of the record, and the commenters thought the time should be reduced to 60 days or less after the close of the record.

NRC Response: The Commission shares with the commenters the goals of regulatory effectiveness and efficiency in licensing and the conduct of hearings. The Commission has monitored - even before the recent adoption of the model milestones in Part 2 (70 FR 20457; April 20, 2005) - the Atomic Safety and Licensing Board adherence to the Commission's direction in its current policies on adjudication. See *Policy Statement on the Conduct of Adjudications*, CLI-98-12, 48 NRC 18 (July 28, 1998), 63 FR 41872 (August 5, 1998); *Statement of Policy on Conduct of Licensing Proceedings*, CLI-81-8, 13 NRC 452 (May 20, 1981), 46 FR 28533 (May 27, 1981).

However, the Commission does not believe that it is appropriate, given the lack of any Commission experience in the conduct of proceedings for either the issuance of combined licenses or the § 52.103 hearings, to make any rulemaking changes in Part 2 to explicitly address the conduct of combined license proceedings. In particular, the Commission does not

believe that it is appropriate, in light of the commenter's failure to specify any particular problem with the Atomic Safety and Licensing Board's implementation of the set of model milestones in any of the current early site permit proceedings (or indeed, in any other proceeding), to consider establishing by rule a set of model milestones, binding schedules, or accelerated time periods for the filing of specific pleadings or the issuance of presiding officer orders and decisions, which would be specific to early site permits, combined license issuances, or to § 52.103 hearings.

The Commission is considering other approaches for addressing this matter, either through issuance of generic guidance to the Atomic Safety and Licensing Board Panel, or through case-specific Commission action. The Commission also intends to continue its active oversight of the Atomic Safety and Licensing Board. The Commission believes that these actions will be sufficient in the near term to ensure regulatory effectiveness and efficiency in the hearing process for the expected early site permit and combined license applications expected in the near term. Accordingly, the Commission declines to adopt any of these commenters' proposal at this time, and no change to any part of the final rule has been made as the result of the comment. The Commission may adopt one or more of the suggested changes in the future, if the Commission determines they are warranted based upon new information or changed circumstances.

Comment 005-22: One commenter disagreed with the requirement for a mandatory hearing for manufacturing licenses. The commenter suggested that the NRC should either leave such hearings to the Commission's discretion or provide the capability for a stakeholder to request a hearing.

NRC Response: See response to Commission Question 15 in Section 4.15 of this document.

Comment 007-15: Several commenters recommended that proposed § 2.105(b)(3)(iv), which states that the notice of intended operation under § 52.103(a) may identify "conditions, limitations or restrictions to be placed on the license in connection with the finding under § 52.103(g)," should be deleted from the final rule. The commenters believed that there is no basis for the NRC to impose license conditions as part of the § 52.103(g) finding. They pointed out that the policy underlying the licensing reforms of the Energy Policy Act of 1992 was that all licensing requirements would be known at the time the COL was issued.

NRC Response: The Commissioner disagrees with the commenters. This provision is intended to permit the NRC to allow interim operation if there is either: (i) a matter of ITAAC compliance that may be resolved during a period of fuel loading and/or interim operation under appropriate conditions, limitations or restrictions; or (ii) the NRC determines that there is a significant matter of non-compliance with the Commission's regulations that would otherwise form the basis for an order suspending operation in the absence of such conditions, limitations or restrictions. Thus, if an issue arises that can be corrected by the combined license holder during a period of interim operation under appropriate conditions, limitations or restrictions, the NRC can permit interim operation without undue delay. Interim operation is specifically provided for in Section 189.a(1)(B)(iii) of the AEA, which was adopted as Section 2808 of the Energy Policy Act of 1992. The commenters presented no legal argument supporting its position that inclusion of conditions, limitations or restrictions as part of a § 52.103 finding to permit interim operation is prohibited by the Energy Policy Act of 1992.

Comment 013-7: A commenter recommended that NRC should affirmatively control the COL hearing process including use of Commission-imposed and enforced firm schedules for completion of hearings and timely issuance of decisions. The commenter commends the Commission's effectiveness in controlling the Louisiana Enrichment Services uranium enrichment facility licensing by the adoption of detailed adjudicatory milestones in that case (CLI-04-03, dated January 30, 2004).

NRC Response: The Commission disagrees with the commenter's suggestion, to the extent that it calls for adoption of firm schedules by rulemaking. The Commission has already adopted Model Schedules, and requirements in §§ 2.332 and 2.334 for presiding officers to develop a specific schedule in each proceeding based upon the applicable Model Schedule, and to inform the Commission when there will be a delay of more than 45 days in meeting any of the dates for the major activities in the schedule for the proceeding. Furthermore, the Commission intends to maintain its current close oversight of hearings conducted by the Atomic Safety and Licensing Board. The Commission considered the arguments in favor and against the adoption of mandatory schedules when it rejected mandatory schedules and adopted the Model Milestones, see 70 FR 20457 (April 20, 2005). The commenter presented no reason why the Commission should revisit its decision, and perhaps most importantly did not identify any example where the Atomic Safety and Licensing Board has failed to adhere to the Model Milestones or the requirements of §§ 2.332 and 2.334. In the absence of any cogent reason in favor of abandoning the approach we adopted less than 2 years ago, the Commission rejects the commenter's suggestion.

Comment 007-27: Several commenters recommended that the proposed provision in § 2.104(d)(1)(v) [cited by commenter as § 2.104(d)(v)], which would impose requirements for an ESP applicant to demonstrate technical qualifications, should be deleted. The commenters objected to these additional requirements on ESP holders because they are not authorized to conduct any safety-related construction activities.

NRC Response: The Commission does not agree with the commenter that a technical qualifications determination of an early site permit applicant is unnecessary because the holder is not authorized to perform "safety-related" construction. The early site permit applicant is responsible for other activities, having a public health and security or common defense and security, for which a technical qualifications finding is necessary. For example, the early site permit holder is required to provide a safety assessment of the site on which the facility may be located, see § 52.17(a)(1)(ix), a description of the quality assurance program to be applied to site-related activities for design, fabrication, construction, and testing of structures, systems and components that may be constructed, see § 52.17(a)(1)(ix), and at minimum provide physical characteristics of the site that could pose a significant impediment to the development of an emergency plant, and measures that would mitigate or eliminate such significant impediments, see § 52.17(b)(1). Such activities, if performed in a technically-inadequate manner, may have a significant impact on public health and safety or common defense and security. Accordingly, the Commission concludes that Section 182.a of the AEA requires the Commission to find that the early site permit applicant possesses the necessary technical qualifications for conducting those activities, and rejects the commenter's implicit suggestion that the technical qualifications requirement for early site permit applicants be removed from the final rule.

Comment 007-50: Several commenters objected to the proposed changes to § 2.104 that identify the contents of notices of hearings for construction permit, ESP, and COL proceedings, including findings to be made by the presiding officer in those proceedings. The changes do not fully incorporate the NRC's conclusions in its Memorandum and Order CLI-05-17 (July 28, 2005) as to the findings that must be made by the Atomic Safety and Licensing Board for a mandatory hearing. Additionally, the proposed rule does not explain why additional findings should be added to the notice of hearing.

NRC Response: The Commission agrees with the commenter that the proposed changes to § 2.104 does not alter the "ambiguous" language in that was the subject of the Commission's order in Exelon Generation Co., LLC (Early Site Permit for Clinton ESP Site) , et al., CLI-05-17, 62 NRC 5 (2005). The Commission's view is that its decision is sufficiently clear that changes to the rule language which were the subject of the Commission's order, would re-introduce some uncertainty into the regulations. Hence, the Commission did not revise the language to "conform" to the Commission's decision on the distinction between contested versus uncontested "issues," the Commission's admonition against de novo review of uncontested issues by the presiding officer, and the prohibition against an intervenor's prohibition on uncontested matters. On these matters, CLI-05-17 provides clear direction. The Commission believes that a generic change should be accomplished in § 2.104 for all proceedings - not just proceedings involving Part 52 permits and licenses, and such rulemaking is outside the scope of the Part 52 rulemaking. Accordingly, the Commission declines to adopt the commenter's proposed changes to § 2.104.

In retrospect, the Commission agrees with the commenter that the SOC for the proposed rule did not provide rationales for adopting additional findings with respect to the various Part 52 permits and licenses. To explain, the Commission's intent was to ensure that the required findings, as set forth in §§ 2.104, 51.105, 51.105a and 51.107, are consistent with the necessary findings which must be made under relevant provisions of the AEA. For example, the findings on early site permits (which may include ITAAC) and combined licenses include a finding with respect to ITAAC, are required by or are consistent with Section 185.b.; and the findings on "technical qualifications" are required by, or are consistent with § 182.a of the AEA. In addition, the Commission added language that reflects the findings set forth in §§ 52.24 and 52.97. For example, the proposed § 2.104(d)(1)(ii) finding specified for early site permits on necessary notifications is drawn from current § 52.24 (which was proposed to be retained in proposed § 52.24(a)(2). The Commission does not regard the incorporation of the findings in §§ 52.24 and 52.97, which have already been approved by the Commission in the 1989 Part 52 rulemaking, as either expanding or contracting in any substantive manner the issues for which findings must be made under § 2.104, or otherwise introducing a new legal problem or ambiguity. The commenters do not appear to have identified any specific legal problem with the proposed findings; rather, they were simply seeking Commission explanation for the changes. Accordingly, the Commission has not made any changes to the final rule as a result of these comments. However, if any commenter, upon reflection, believes that there is a new legal problem introduced by the changes to § 2.104, they may submit a petition for rulemaking, requesting the Commission to correct the matter.

Comment 007-43: The commenters recommend that the NRC retain Appendix Q in Part 52, as well as in Part 50. The commenters stated that while no applicant has yet expressed an intent to use the early site review process in Appendix Q or the process in Subpart F to Part 2

for partial decisions on site suitability issues, these processes may provide important flexibility for early and efficient consideration of site suitability issues for COL applicants. There is no reason to eliminate this flexibility, and no harm is caused by allowing Part 52 applicants to utilize these provisions.

Both of these regulations allow critical path site issues to be reviewed by NRC in advance of the submission of a COLA, in cases where the applicant's schedule or other considerations does not allow it to complete the ESP process in advance of the COLA. Further, utilization of Appendix Q or Subpart F in the context of a COLA could allow the NRC staff to more efficiently utilize its resources to focus early review of site issues only on those issues sought by the applicant, rather than the full scope of issues required by an application for an ESP.

In the August 2005 draft of the proposed rule, changes were indicated in 10 CFR Part 2, Subpart F that would have allowed the Subpart to be used in the Part 52 COL process. This change is not part of the proposed rule noticed in the *Federal Register*. Thus, one could (erroneously) conclude that Part 2, Subpart F, is only applicable to the Part 50 construction permit process. The commenters suggest that the August 2005 draft revisions to Subpart F be incorporated into the final Part 52 rule to clarify its continuing availability to Part 52 applicants.

NRC Response: The final rule includes changes to § 2.101 and 10 CFR Part 2, subpart F, which clarify its applicability to Part 52 combined license applicants.

Comments 007-62 and 007-73: Several commenters noted that Section 625 of the Energy Policy Act of 2005 eliminated the antitrust review of an applicant for a license to construct or operate a utilization facility or production facility under Section 103 or 104.b of the Atomic Energy Act of 1954, as amended. Thus, § 2.104(l) of the proposed rule should be deleted, and provisions related to antitrust reviews in §§ 50.33a, 50.41(c), 50.42(b), and 50.54(g) of the existing rules should be deleted.

NRC Response: The Commission agrees with the commenters that § 2.104(l) in the proposed rule (which represented a redesignation of former § 2.104(d)) need not be included in the final rule. Section 625 of the Energy Policy Act of 2005 (2005 EPA) removed the need for antitrust reviews for production and utilization facilities licensed under Section 103 or 104.b. of the AEA whose applications are filed after the date of enactment of the 2005 EPA. For the same reason, the Commission also agrees with one commenter that §§ 50.41(c) and 50.42(b), which address antitrust review of applications, should be removed from Part 50. Accordingly, the Commission has not included § 2.104(l), and has removed §§ 50.41(c) and 50.42(b). The latter two changes may be made in the final rule without notice and opportunity for public comment, inasmuch as these changes are non-discretionary rulemakings intended to comply with the 2005 EPA. Accordingly, in accordance with the APA, 5 U.S.C. 553(b)(3)(B), the Commission finds that notice and public comment on these changes are unnecessary.

However, the Commission disagrees with the commenters' suggestion that § 50.54(g) should be deleted to be consistent with Section 625 of the 2005 EPA. Section 50.54(g) continues to be applicable for existing licensed nuclear power plants with antitrust conditions included in their operating licenses. Accordingly, it is not appropriate to remove this section from the Commission's regulations as part of the Part 52 rulemaking.

Comment 007-80: Several commenters supported the proposed changes to §§ 2.1, 2.100, 2.105, 2.106, 2.109, 2.390, and 2.800.

NRC Response: No response necessary.

5.7 Changes to 10 CFR Part 10

No comments received.

5.8 Changes to 10 CFR Part 19 – Notices, Instructions and Reports to Workers: Inspection and Investigations

Comment 007-17: Several commenters objected to the provisions in proposed § 52.5(a) and parallel provisions in Part 19 that apply to employee protection requirements to design certification applicants and design approval applicants. The commenters recommended that changes suggested for Part 52 also should be made in Part 19.

NRC Response: The NRC disagrees with the comment that application of employee protection requirements to design certification applicants and applicants for design approval “is inappropriate and unauthorized under Section 211 of the Energy Reorganization Act (the Act). As stated in the Supplementary Information section of the proposed rule, the NRC believes that its regulatory authority under Section 211 and Section 401 of the 1974 ERA is much broader than the current scope of Part 19. The anti-discrimination proscriptions in Section 211 of the ERA apply to any “employer,” which the NRC regards as including non-licensee entities otherwise regulated by the NRC, such as applicants for and holders of standard design approvals, and applicants for standard design certifications. The Commission believes that the use of the term, “includes,” in paragraph (a)(2) of Section 211 of the 1974 ERA was not intended to be an exclusive list of the persons and entities subject to the anti-discrimination provisions in that section. The House Report on H.R. 776, which was adopted by Congress as the Energy Policy Act of 1992, states:

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

H.Rep. No. 102-474, Part 8, 102d Congress, 2d Sess., at 78-79 (1992) (emphasis added). There was no discussion of the statutory language in the conference report. H.R. Conf. Rep. No.102-1018, 102d Cong., 2d Sess. (1992). Commenters did not provide any reason why the Commission’s interpretation of “includes” is incorrect. The Commission’s interpretation is reasonable because design certifications and design approvals help to form the basis for NRC safety determinations with respect to licensing of nuclear power plants referencing the design certifications or design approvals. Accordingly, in the absence of any showing that the Commission’s interpretation is incorrect or otherwise unreasonable, the NRC rejects the comments and has made no changes in the final rule. The NRC also does not agree with the commenters’ suggestion that § 52.5(a) should apply only during those periods in which the applicant for design certification or design approval is actively engaged in regulated activities. The NRC believes that employees should be able to raise safety concerns related to a design

approval or design certification at any time without fear of retaliation.

Comment 007-41: Several commenters recommended deletion of § 19.11(b)(2), which would require various applicants to post “The operating procedures applicable to the activities regulated by the NRC which are being conducted by the applicant or holder.” The commenters pointed out that applicants and holders may have volumes of operating procedures and posting them all would be impractical.

NRC Response: The NRC does not agree that proposed § 19.11(b)(2) should be deleted. Proposed § 19.11(d) states that, if posting of a document is not practicable, the licensee or regulated entity may post a notice which describes the document and states where it may be examined.

5.9 Changes to 10 CFR Part 20

No comments received.

5.10 Changes to 10 CFR Part 21 – Reporting of Defects and Noncompliance

Comment 007-3: Several commenters opposed the proposed changes to Part 21, which would expand the applicability of the provisions to applicants. The commenters believed that the changes are contrary to the Energy Reorganization Act, and the expansion of Part 21 is unnecessary, given the provisions in proposed § 52.6(a).

NRC Response: The NRC disagrees with this comment. The proposed rule required applicants for early site permits, design certifications, and standard design approvals to also meet the Part 21 reporting requirements. A detailed discussion on the Commission’s rationale for imposing these requirements is provided in Section V.J of the Federal Register notice (Supplementary Information).

Part 21 and ESPs

Comments 007-4 and 005-2: Several commenters stated that given the absence of design information for ESPs, which do not require designation of a specific design to be located on the site in question, Part 21 should not be applicable to an ESP applicant or an ESP holder. Commenters argued that under Part 21, only noncompliances and defects in basic components involving “substantial safety hazards” were reportable. They stated it might be impossible for an ESP applicant or holder to determine whether a particular deficiency or noncompliance in siting information created a “substantial safety hazard” because it may not have a design against which to make the determination. They stated that a nonconservatism or error in siting issues does not create a substantial safety hazard, because plant designs typically include significant margins to account for such errors. Commenters believed that absent final design information, an error in siting information would not meet the definition of a reportable condition, and there would therefore be no practicable method for ESP applicants or holders to determine whether an error in siting information created a substantial safety hazard.

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

detailed discussion on the Commission's rationale for imposing these requirements in the final rule is provided in Section V.J of the supplementary information in the Federal Register Notice.

Part 21, Section 50.55(e), and Section 52.6(b) and the Period Prior to Submission of a COL Application

Comment 007-5: Several commenters believed provisions in Part 21, § 50.55(e), and § 52.6(b) would impose “inappropriate and inconsistent” reporting obligations on ESP holders, holders of standard design approvals, and design certification applicants during the period from issuance of the NRC approval to the time of reference of the approval in a COL application. The commenters cited the Supplementary Information accompanying the proposed rule (71 FR 12818) in which the NRC noted that it has changed its position from the 2003 Notice of Proposed Rulemaking and provided the reasons why. The commenters countered that the “regulatory life” of an early site permit, standard design approval, and standard design certification had no regulatory significance until and unless one of the Part 52 actions was referenced in a COL application. They submitted that no “substantial safety hazard” could exist unless and until those actions were referenced in a COL application, making it “unduly burdensome” for these entities to maintain a reporting program when no activities could create a substantial safety hazard under § 206 of the ERA.

Commenters stated that it was not necessary for an ESP applicant to identify any particular design, and, even if a design were specified, it was possible that the design would not have been fully developed at the time the ESP was issued. They noted that under such circumstances, it likely would be impossible for an ESP holder to determine whether a particular deficiency or noncompliance created a “substantial safety hazard.” As a result, the commenters believed it would be impossible for an ESP holder to determine whether to report the deficiency or noncompliance under Part 21, § 50.55(e), or § 52.6(b). The commenters noted that NRC appeared to recognize this point (Supplementary Information at 71 FR 12820) but had not crafted the proposed rule to accommodate it. The commenters mentioned that in particular, there was nothing in the proposed provisions in Part 21, § 50.55(e), or § 52.6(b) that would allow an applicant for design certification or design approval or an ESP holder to defer reporting until such time that the standard design or ESP was referenced in a COL application. They argued the proposed rule must be modified to make it consistent with the accompanying guidance and Supplementary Information.

Commenters believed that it would be “inappropriate” for the NRC to apply Part 21 to the applicant for a design certification. They noted a design certification was a rule, not a license, and the design certification applicant would have no proprietary interest in the design certification rule. They contended that the design certification applicant should have no responsibilities under Part 21 because they might not be the vendor used by the COL applicant. Furthermore, the commenters stated that both Part 21 and § 206 applied to companies supplying basic components for a nuclear plant, meaning that if the design certification applicant contracted with the COL applicant to supply basic components, the design certification applicant would be covered by the “flow down” provisions in Part 21.

Commenters contended that the extension of NRC’s reporting requirements implementing § 206 of the ERA to Part 52 licensing and approval processes should be consistent with three key principles: (1) NRC regulatory requirements implementing § 206 of the ERA should be a

legal obligation throughout the entire “regulatory life” of a NRC license, a standard design approval, or standard design certification; (2) reporting of defects or failures to comply with associated substantial safety hazards should occur whenever the information on potential defects would be most effective in ensuring the integrity and adequacy of the NRC’s regulatory activities under Part 52 and the activities of entities subject to the Part 52 regulatory regime; and (3) each entity conducting activities within the scope of Part 52 should develop and implement procedures and practices to ensure that it fulfills its § 206 of the ERA reporting obligations in an accurate and timely manner.

NRC Response: The NRC agrees, in part, with this comment. The NRC’s implementation of Section 206 of the ERA is consistent with the three key principles, which are discussed in Section V.J of the Federal Register notice (Supplementary Information). Regarding the second principle, reporting may be delayed if there is no immediate consequence or regulatory interest in prompt reporting and delayed reporting will occur when it is necessary to support effective, efficient, and timely action. Therefore, the reporting of defects or failures to comply may be delayed until the time that the Part 52 process (design approval, design certification, or ESP) is first referenced. However, the NRC does not agree with the commenter’s claim that a design certification applicant should have no responsibilities under Part 21. The design certification applicant has supplied the design information and bases for the certified design and the NRC and any applicant or licensee referencing the certified design need to be notified of defects regardless of whether that applicant is the selected vendor for the applicant or licensee that has referenced the design certification.

Part 21 Retroactive Application to Existing ESP Applicants and Design Certification Applicants

Comment 007-6: Several commenters believed that the proposed changes to Part 21 would impose retroactive obligations on the existing ESP and design certification applicants. They listed several reasons why such retroactivity would be inappropriate:

(1) Application of the proposed provision to existing applicants would be unworkable, since they have already issued contracts and cannot reasonably amend them to impose Part 21 responsibilities on contractors and subcontractors.

(2) Imposition of this proposed provision on the existing contracts of applicants would constitute an unconstitutional ex post facto regulation under Article I, Section 9 of the U.S. Constitution.

These commenters argued that the NRC, at a minimum, needed a grandfather clause to exempt existing applicants from the need to meet the new requirements as applied to contracts and activities entered into prior to the effective date of the new regulation.

NRC Response: The Commission proposed Part 21 reporting requirements on applicants for early site permits, design certifications, and standard design approvals in the proposed rule. A detailed discussion on the Commission’s rationale for imposing these requirements in the final rule is provided in Section V.J of the supplementary information in the Federal Register Notice.

Part 21 and Manufacturing Licenses

Comment 005-21: A commenter expressed confusion as to how Part 21 would apply to a ML

until the manufactured reactor was installed in a nuclear power plant. The commenter was also unclear as to how the NRC could equate issuance of an ML with “construction” on p. 12820 because nothing would be constructed until the reactor was transported to and installed in a plant.

NRC Response: The holder of a manufacturing license should consider itself equivalent to the holder of a construction permit with respect to the reactor being manufactured, for purposes of determining its obligations under 50.55(e) and Part 21. For example, with respect to design, the holder of a manufacturing license is responsible for evaluating any defects in the design of the reactor to be manufactured (as approved in the manufacturing license), in order to determine if reporting is necessary under 50.55(e). Similarly, with respect to a manufacturing - e.g., welding of a reactor vessel nozzle - the holder of the manufacturing license is responsible for evaluating any defects in that welding, in order to determine if reporting is necessary under 50.55(e).

The fact that the holder of a manufacturing license does not “construct” the nuclear power reactor is of no consequence in the application of the reporting requirements imposed by Section 206 of the Energy Reorganization Act of 1974, as amended, inasmuch as the requirements imposed by Section 206 do not depend upon whether an activity constitutes or otherwise involves “construction.”

5.11 Changes to 10 CFR Part 25

No comments received.

5.12 Changes to 10 CFR Part 26

No comments received.

5.13 Changes to 10 CFR Part 51 – Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions

NEPA and Connected Actions

Comments 002-3, 002-6, 002-7, 002-8, and 012-1: Several commenters believed that an ESP and COL met the National Environmental Policy Act (NEPA) definition of “connected actions,” and should therefore not require the preparation of a new EIS for the second of the two connected actions, or a revalidation of previous findings if neither the applicant nor others identify significant new information. Commenters stated that under applicable case law, there was no requirement to prepare a new EIS for the latter of the two connected actions that were previously evaluated together in a single EIS. The commenters stated that the EIS prepared at the ESP stage serves as the EIS for issuance of both the ESP and COL. Commenters stated that the ESP EIS included an evaluation of the environmental impacts related to issuance of a COL inasmuch as it considered the environmental impact of plant construction and operation, and thus existing Part 52 regulations properly recognize that a COL application “need not contain information or analyses submitted to the Commission in connection with the ESP” (10 CFR 52.79(a)(1)). One commenter stated the following: “As a threshold matter, the CEQ regulations are not binding on the NRC as an independent agency when the agency has not

expressly adopted them.” (Limerick Ecology Action, Inc. v. NRC, 869 F.2d 719,725,743, 3d Cir. 1989; 49 FR 9352, March 12, 1984). The commenter contended that the CEQ regulations explain that connected actions “mean that they are closely related and therefore should be discussed in the same impact statement” (40 C.F.R. § 1508.25(a)(1)). Since an ESP is a partial construction permit and resolves whether a site is suitable for construction and operation of new units, it is obviously closely related to a COL. Further, under the CEQ regulations, actions are connected if they are “interdependent parts of a larger action and depend on the larger action for their justification” (40 C.F.R. § 1508.25(a)(1)(iii)). If a COL is a partial construction permit, it is obviously an initial step in a larger action and is undertaken only to further decisions and actions on whether new nuclear units should be built. Under applicable case law, there is no requirement to prepare a new EIS for the latter of two connected actions that were previously evaluated together in a single EIS. (Village of Grand View v. Skinner, 947 F.2d 651, 656-57, 2d Cir. 1991)

Several commenters stated that for COL applications that reference an ESP, a supplemental EIS that incorporates by reference the findings and conclusions of the ESP final EIS should be permissible when new significant information has been discovered. The commenters stated that this would be consistent with the proposed new § 51.75(c)(1). To promote better understanding of when certain documents are appropriate, commenters suggested the NRC clarify that § 51.20(b), both existing and proposed, allows preparation of either an EIS or an EIS supplement for both an ESP application and a COL application.

NRC Response: The Commission does not agree with the commenters’ analysis. The commenters’ argument appears to assume in general that if two Federal actions are connected and the EIS prepared for the first action is complete and accurate, then a second EIS need not be prepared for the second action. While the Commission does not disagree with this general argument, the Commission, for two reasons, does not believe it will apply in all circumstances in which a COL application references an ESP.

First, in accordance with 10 CFR 51.50(b), an ESP applicant need not address the economic, technical, and other benefits and costs of the proposed action, or an analysis of other energy alternatives. If an ESP applicant chooses to omit this information from its Environmental Report, the NRC will not address it in the ESP EIS. Thus, the ESP EIS may not be complete with respect to the benefits and costs of the proposed action or energy alternatives, and a supplement to the EIS would then be necessary to discuss such matters if a COL application references the ESP. The commenters do not cite any case to address this situation.

Second, between the time the NRC issues an ESP EIS and a COL applicant references the ESP, significant information not reflected in the ESP EIS may be identified. In light of that significant new information, the ESP EIS would thus not be accurate with respect to the construction and operation of a power reactor proposed in the COL application, and a supplement to the ESP EIS would then be necessary. The commenters acknowledge this principle, and agree that a supplemental EIS should be prepared in connection with the COL application if new and significant information is identified.

The Commission concludes that treatment of an ESP and a COL application referencing that ESP as connected actions does not appear to negate the need for preparing an EIS supplement in connection with the COL application in at least some circumstances. The NRC continues to believe that it is not necessary to require that all topics be covered in a single EIS

at the ESP stage, and that topics such as alternative energy sources and need for power may be treated in an EIS supplement at the COL application stage when the detailed planning for the project is completed. As the commenters note, new and significant information may also prompt the preparation of a supplement to the ESP EIS in connection with the COL application. The Commission has modified the final rule to limit the preparation of a supplementary EIS to those situations. Since the Commission believes that some issues may not be ripe for consideration at the ESP stage, as explained above, and an ESP EIS need not address such issues, the Commission is declining to take a position on whether the granting of an ESP and the granting of a COL referencing that ESP are connected actions.

Nonetheless, if detailed planning and associated environmental information is in fact complete when an ESP application is filed, there is no bar to the NRC to prepare, at the ESP stage, an EIS that resolves all environmental matters associated with construction and operation of a power reactor at the ESP site, including the benefits of such construction and operation (e.g., need for power), and alternative energy sources. The Commission may then rely on that EIS at the COL stage, provided that new and significant information has not been identified. The Commission need not label the ESP and COL as connected actions to adopt this procedure. Accordingly, the NRC has modified the final rule to allow for an ESP EIS to serve as the EIS for a COL application referencing the ESP without supplementation under such circumstances.

NEPA Non-compliance

Comments 008-5 and 011-18: Several commenters expressed concern that the proposed rules would not require a new NEPA process for COL applicants citing an ESP. Commenters stated they were unsure whether NRC was living up to its obligations under NEPA by not taking a “hard look” at both actions separately.

NRC Response: The final rule does provide a “NEPA process” for COL applications referencing an ESP. The NEPA process employed to evaluate issuance of a COL (in 10 C.F.R. § 51.75(c)) will ensure that the NRC takes a hard look at all the environmental impacts resulting from facility construction and operation, which are the impacts associated with COL issuance. The Commission anticipates that it will evaluate the bulk of these impacts in the ESP EIS, leaving only a limited scope of issues for NRC evaluation at the COL stage, along with any new and significant information identified in the interim. At the COL stage, however, there is no need to re-evaluate an impact that was fully evaluated at the ESP stage and for which new and significant information has not been identified. To do so would be to waste the resources of all stakeholders and would not further the purposes of NEPA. Accordingly, if the ESP EIS resolves all environmental issues and no new and significant information has been identified at the COL stage, the ESP EIS will serve as the COL EIS. Under such circumstances, the NRC NEPA process at the COL stage will inquire into whether there is any new and significant information on the matters discussed in the ESP EIS. If new and significant information is identified at the COL stage, a supplemental EIS will be developed to evaluate that information.

While the commenters appear to believe that separate EISs are required for each of the proposed actions (issuance of an ESP and a COL with respect to the ESP site), NEPA does not require this. Rather, the Part 52 licensing model, with respect to ESPs and COLs referencing them, is akin to evaluation of a project at an early stage, with subsequent evaluation at a later stage, as described in the CEQ regulations at 40 C.F.R. § 1508.28(b). As indicated in

§ 1508.28(b), such a process is appropriate when it helps the agency to focus on the issues that are ripe for decision and exclude from consideration issues already decided or not yet ripe. The Commission intends to focus its environmental reviews in a similar manner. Accordingly, the Commission concludes that the final rule will ensure compliance with NEPA.

Comment 005-27(b): A commenter noted that NRC indicates that the environmental impacts associated with the manufacture of a reactor under an ML are not relevant to the NRC's determination; however, the hearing for an ML would consider "environmental, technical, economic, and other" issues associated with SAMDAs. Moreover, the rule would require a finding as to whether the NRC staff has been able to identify "all reasonable SAMDAs" for such a reactor. The commenter asked what standard NRC will use to determine what is a "reasonable SAMDA?" The commenter stated that, to the extent that similar language appears in other parts of new or revised sections of 10 CFR Part 51 (or other parts of 10 CFR), it should be removed.

NRC Response: The Commission disagrees with the commenter's suggestion that the requirements for consideration of severe accident mitigation design alternatives (SAMDAs) be removed from § 51.105a. The only reason provided by commenter in support of its proposal is that the rule does not specify what "reasonable" SAMDAs should be considered. The Commission believes that the Commission's determinations with respect to consideration of SAMDAs in the four final standard design certifications approved by the Commission, the NRC's caselaw on consideration of SAMDA in operating license proceedings throughout the years, and more general federal caselaw on "reasonable alternatives" under NEPA, are sufficient yardsticks for determining the proper scope of SAMDAs for a manufacturing license. No changes were made to the final rule as the result of this comment.

Comment 007-50: Several commenters objected to the proposed changes to §§ 51.105, 51.105a, and 51.107 that identify the contents of notices of hearings for construction permit, ESP, and COL proceedings, including findings to be made by the presiding officer in those proceedings. The changes do not fully incorporate the NRC's conclusions in its Memorandum and Order CLI-05-17 (July 28, 2005) as to the findings that must be made by the Atomic Safety and Licensing Board for a mandatory hearing. Additionally, the proposed rule does not explain why additional findings should be added to the notice of hearing.

NRC Response: The Commission agrees with the commenter that the proposed change to do not change, or repeat, the "ambiguous" language in that was the subject of the Commission's order in Exelon Generation Co., LLC (Early Site Permit for Clinton ESP Site) , et al., CLI-05-17, 62 NRC 5 (2005). The Commission's view is that its decision is sufficiently clear that changes to the rule language which were the subject of the Commission's order, would re-introduce some uncertainty into the regulations. Hence, the Commission did not revise the language to "conform" to the Commission's decision on the distinction between contested versus uncontested "issues," the Commission's admonition against de novo review of uncontested issues by the presiding officer, and the prohibition against an intervenor's prohibition on uncontested matters. On these matters, CLI-05-17 provides clear direction. The Commission believes that a generic change should be accomplished in § 2.104 for all proceedings - not just proceedings involving Part 52 permits and licenses, and such rulemaking is outside the scope of the Part 52 rulemaking. Accordingly, the Commission declines to adopt the commenter's proposed changes to § 2.104.

In retrospect, the Commission agrees with the commenter that the SOC for the proposed rule did not provide rationales for adopting additional findings with respect to the various Part 52 permits and licenses. To explain, the Commission's intent was to ensure that the required findings, as set forth in §§ 2.104, 51.105, 51.105a and 51.107, are consistent with the necessary findings which must be made under relevant provisions of the AEA. For example, the findings on early site permits (which may include ITAAC) and combined licenses include a finding with respect to ITAAC, are required by or are consistent with Section 185.b.; and the findings on "technical qualifications" are required by, or are consistent with § 182.a of the AEA. In addition, the Commission added language that reflects the findings set forth in §§ 52.24 and 52.97. For example, the proposed § 2.104(d)(1)(ii) finding specified for early site permits on necessary notifications is drawn from current § 52.24 (which was proposed to be retained in proposed § 52.24(a)(2)). The Commission does not regard the incorporation of the findings in §§ 52.24 and 52.97, which have already been approved by the Commission in the 1989 Part 52 rulemaking, as either expanding or contracting in any substantive manner the issues for which findings must be made under § 2.104, or otherwise introducing a new legal problem or ambiguity. The commenters do not appear to have identified any specific legal problem with the proposed findings; rather, they were simply seeking Commission explanation for the changes. Accordingly, the Commission has not made any changes to the final rule as a result of these comments. However, if any commenter, upon reflection, believes that there is a new legal problem introduced by the changes to § 2.104, they may submit a petition for rulemaking requesting the Commission to correct the matter.

Comment 007-60: Several commenters suggested that proposed § 51.71(d) should be made consistent with § 51.50(c)(1)(i). COL applicants that reference an ESP are not required to demonstrate that "the site falls within the site characteristics specified within the early site permit."

NRC Response: NRC Response: The NRC agrees and has removed the referenced language in the final rule.

Comment 007-66: Several commenters recommended that proposed §§ 51.50(b) and 51.71(d) be revised to refer to characteristics that fall within the "site characteristics and design parameters," rather than "site parameters."

NRC Response: The NRC agrees that the proposed rule language referenced by the commenter should be revised and has done so in the final rule.

Comment 007-85: Several commenters supported the proposed changes to §§ 51.50, 51.71(d), and 51.75(c)(1).

NRC Response: No response necessary.

Comment 008-3: A commenter believed that the NRC should demand that applicants consider only good sites and then choose one of the best sites they considered. Sites with problems should not be approved.

NRC Response: This NRC will not approve any site for eventual construction and operation of a nuclear power plant that does not meet NRC regulations.

Comment 011-6: A commenter suggested that §§ 51.50(c)(2) and (c)(3) and 51.75(c)(2) and (c)(3) should explain what to do when sites are not within parameters.

NRC Response: The NRC does not agree that it is necessary to revise §§ 51.50(c)(2) and (c)(3) and 51.75(c)(2) and (c)(3) to explain what to do when a COL applicant that references either a design certification or a manufactured reactor cannot demonstrate that the site characteristics for the COL site fall within the site parameters postulated in the design certification or manufacturing license. The NRC believes this level of information is more appropriate for inclusion in regulatory guidance documents such as Draft Regulatory Guide (DG) 1145, "Combined License Applications for Nuclear Power Plants (LWR Edition)."

Comment 011-7: One commenter believed that §§ 51.50(c)(1) and 51.71(d) should refer to information on issues that were "not resolved."

NRC Response: The NRC agrees with the commenter and has revised the rule text in proposed §§ 51.50(c)(1) and 51.71(d) [final § 51.75(c)(1)] to refer to issues "not resolved in the early site permit proceeding."

Comment 011-8: A commenter noted that §§ 51.50(c)(1)(iii), 51.71(d), 51.75(c)(1), and 51.107(b) require applicants to submit new and significant information on the site or design, but the commenter asked about changes offsite affecting the environmental impacts.

NRC Response: The requirement to submit new and significant environmental information has been modified in the final rule based, in part, on public comments. The Commission believes that the changes that occur offsite, which could affect the analysis of environmental impacts of construction and operation considered in the ESP, need to be considered to determine whether the new information is relevant to the NRC's prior analysis and whether it is also significant. The rule language has been modified to capture this concept. In the final rule, the requirement is that COL applicants referencing an ESP must submit any significant new information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding. This revised wording does not limit the new and significant information to the site or design, but rather, focuses on issues resolved in the ESP proceeding.

Comment 011-9: A commenter referred to § 51.50(c) (page 12880), and asked if the second sentence in this section should include the phrase "as modified in this paragraph..." similar to § 51.50(b).

NRC Response: The NRC agrees with the commenter and has revised the first sentence in § 51.50(b) to include the phrase "as modified in this paragraph," such that the final provision reads, "Each applicant for an early site permit shall submit with its application a separate document, entitled "Applicant's Environmental Report—Early Site Permit Stage," which shall contain the information specified in §§ 51.45, 51.51, and 51.52, as modified in this paragraph."

Comment 011-10: A commenter believed that the change in § 51.53(c)(3) to include holders of a combined license issued before June 30, 1995, appears nonsensical because there are not any combined license holders.

NRC Response: While there are no plants with a combined license issued before June 30,

1995, the date in this portion of the rule relates to the effective date of the Generic Environmental Impact Statement for License Renewal of Nuclear Plants (GEIS, NUREG-1437); the GEIS provides the basis for the analysis of environmental effects of license renewal. Therefore, whenever the GEIS is updated and the results of the update is codified in an amended rule, this date will change. The reason that this section was changed at this time was to ensure that a license holder of a COL could also seek license renewal under the provisions of 10 CFR Part 54; the environmental effects of license renewal for a plant authorized to operate under a combined license would also be considered in the periodic updates to the GEIS; this ensures that combined licenses can be renewed in the same way as operating licenses provided that the facility was considered in the GEIS.

Comment 011-11: A commenter asked whether § 51.71(d) should refer to an “obviously superior” alternative site.

NRC Response: The NRC agrees that the subject provision in proposed § 51.71(d) [final § 51.75(b)] should refer to an “obviously superior” alternative site. The NRC has revised this provision in the final rule to read, “The draft environmental impact statement must focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the site characteristics, and need not include an assessment of the benefits (for example, need for power) of the proposed action or an evaluation of other alternative energy sources unless considered by the applicant, but must include an evaluation of alternative sites to determine whether there is an obviously superior alternative to the site proposed.”

Comment 011-12: A commenter noted that § 51.71(d) (page 12882) refers to a supplemental EIS used for a COL referencing an ESP. The commenter disagreed and does not believe it should be a supplemental EIS because the regulations elsewhere appear to require a complete EIS for a COL. The commenter noted that the wording about a supplemental EIS appears elsewhere in the rule as well.

NRC Response: The Commission does not agree with the commenter that the regulations require a completely new EIS at the COL stage when the applicant is referencing an ESP. To the extent existing regulations are unclear on this point, the Commission has made changes to make explicit that only a supplement to the ESP EIS need be prepared if the COL application references an ESP. Further, the Commission has added provisions to allow the ESP EIS to serve as the COL EIS under certain limited circumstances, as discussed below.

In most circumstances, the NRC will prepare an EIS supplement in connection with a COL application referencing an ESP and not an entirely new EIS. The NRC believes that topics such as alternative energy sources and need for power may be deferred at the ESP stage and treated in an EIS supplement at the COL application stage when the detailed planning for the project is completed. Similarly, an ESP applicant need only submit information on the effects of facility construction and operation to a depth sufficient to evaluate alternative sites, and an EIS supplement may then be necessary at the COL stage to fully disclose all impacts. Also, between the time the NRC issues an ESP EIS and a COL applicant references the ESP, significant information not reflected in the ESP EIS may be identified. In all these circumstances, which the Commission anticipates will be the usual case, the NRC will prepare a supplemental EIS. Nonetheless, if detailed planning and associated environmental

information is in fact complete when an ESP application is filed, there is no bar to the NRC to prepare, at the ESP stage, an EIS that resolves all environmental matters associated with construction and operation of a power reactor at the ESP site, including the benefits of such construction and operation (e.g., need for power), and alternative energy sources. The Commission may then rely on that EIS at the COL stage, provided that new and significant information has not been identified. The NRC believes that it would be satisfying its obligations under NEPA and NRC regulations whether the NRC prepares a supplement to an ESP EIS or not, as circumstances warrant. The NRC has made amendments in the final rule to clarify the requirements to reflect the above discussion.

Comment 011-13: A commenter suggested that the wording of the footnote in § 51.71(d) (page 12883) implies that an impact assessment was available, but then was withdrawn. The commenter suggested revising the language so that it says “is not available from...”

NRC Response: This change to the footnote was unintended. The final rule language preserves the original structure and language.

Comment 011-14: A commenter stated that § 51.75(a), (b), and (c) of the rule is not clear how fuel cycle impacts are handled if the plant design is outside the bounds of Table S-3.

NRC Response: The environmental effects involved in the fuel cycle must be considered for a production and utilization facility; consequently, every environmental report prepared for the construction permit stage (i.e., a CP, an ESP, or a COL) must provide the environmental data and analyze the effects. The bases for considering environmental effects for light-water reactors are prescribed in § 51.51(a). If the plant design attributes for a light-water-cooled nuclear power reactor are not within the environmental data provided in Table S–3, then the environmental report should include a discussion of the significance of the departure. In the case of an other-than-light-water-cooled nuclear power reactor, Table S–3 does not apply and the applicant would need to provide a full description and detailed analysis of the environmental effects of the fuel cycle.

Comment 001-15: A commenter wondered why Table S-4 is not mentioned.

NRC Response: The Commission established the conditions that allows applicants to consider the environmental effects of transportation of fuel and waste codified in Table S–4. While § 51.52 indicates that the applicant’s environmental report must take this information as the basis for its analysis, for reactors that do not meet the conditions enumerated in § 51.52(a), the environmental report would need to provide a full description and detailed analysis of the environmental effects.

Comment 011-16: A commenter asked whether the NRC must determine in § 51.75(c)(1), (2), and (3) that previous analyses are applicable.

NRC Response: Yes, the NRC must determine the applicability of previous analyses, data, and information that can be considered both by applicants and the NRC staff. In the end, as stated in § 51.70(b), the NRC staff will independently evaluate and be responsible for the reliability of all information used in the draft environmental impact statement. Consequently, the applicability and reliability of previous analyses, data, and information must be evaluated.

With respect to the NRC's compliance with the National Environmental Policy Act (NEPA), under the provisions of § 51.29(a), the NRC would use the scoping process to "identify and eliminate from detailed study those issues which are peripheral or are not significant or which have been covered by prior environmental review" and to identify other environmental assessments and impact statements which are "related to but are not part of the scope of the statement under consideration." Tiering allows federal agencies to rely on previous environmental assessments (EAs) and EISs to aid in the presentation of issues, eliminate repetition, or reduce the size of an EIS. The regulations permit the NRC staff to use tiering and incorporation by reference [see 10 CFR Part 51, Subpart A, Appendix A.1.(b)] principles. Analyses, data, and information that existed from prior licensing decisions can be used by the NRC staff provided that it was demonstrated to be reliable and technically applicable to the prospective licensing action.

Comment 011-17: A commenter noted that § 51.107(b) (page 12885) addresses issues "accorded finality under 52.39..." The commenter felt that this wording is not consistent with other sections. The commenter suggested rewording as follows: "issues resolved in the proceeding on the application for issuance of the early site permit..." to be consistent with § 52.39.

NRC Response: The NRC agrees and has revised the language in proposed § 51.107(b) to be consistent with the language in § 52.39 in the final rule.

5.14 Changes to 10 CFR Part 54

No comments received.

5.15 Changes to 10 CFR Part 55

No comments received.

5.16 Changes to 10 CFR Part 72 – Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste and Reactor Related Greater than Class C Waste

No comments received.

5.17 Changes to 10 CFR Part 73 – Physical Protection of Plants and Materials

Comment 007-86: Several commenters supported the proposed changes to §§ 73.56 and 73.57.

NRC Response: No response necessary.

5.18 Changes to 10 CFR Part 75

No comments received.

5.19 Changes to 10 CFR Part 95

No comments received.

5.20 Changes to 10 CFR Part 140 – Financial Protection Requirements and Indemnity Agreements

Comment 007-71: Several commenters believed that the proposed rule adequately addresses the issue of adding Part 52 applicants and license holders to the scope of Part 140.

NRC Response: No response necessary.

5.21 Changes to 10 CFR Part 170

No comments received.

5.22 Changes to 10 CFR Part 171 – Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Material Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Listed by NRC

Comment 007-72: Several commenters believed that the proposed rule adequately addresses the issue of modifying § 171.15 to reflect that a COL holder shall start to pay annual fees once the Commission has made the finding under § 52.103(g).

NRC Response: No response necessary.

Comment 007-87: Several commenters supported the changes to Part 171.

NRC Response: No response necessary.

5.23 Other General Comments

Comment 008-1: A commenter remarked that it was sensible to change the design certification process now because NRC has learned something over the years. However, the commenter pointed out that it is unknown at this time what a properly-prepared site permit or a combined construction permit and operating license will look like. The commenter asked why NRC hasn't published an example prior to requesting comment on the proposed rule, and argued that the public is not well informed if an example is not published. The commenter questioned whether the permits and licenses are going to be nonspecific, beneficial deals for the industry or specific enough so industry is held accountable for their performance.

NRC Response: This comment addresses issues that are outside of the scope of this rulemaking. The NRC notes that a sample combined license can be found in SECY-00-0092, "Combined License Review Process," dated April 20, 2000 and a sample early site permit can be found in a June 22, 2004 NRC letter to the Nuclear Energy Institute (ML041110012).

Comment 008-4: This commenter was supportive of NRC's plan to treat an approved design

as a final design without changes. However, the commenter noted that it is not clear that it will always do so because of the potential for severe environmental events or changes (e.g., tsunamis, earthquakes, and hurricanes). The commenter asked how these changes could impact the utility of emergency plans prepared years earlier. The commenter also pointed out that population growth is another change that should be considered to ensure old plans (i.e., more than 25 years) are still effective.

NRC Response: This comment addresses issues that are outside of the scope of this rulemaking. However, the NRC notes that if changes to communities or landscapes have occurred over time following the initial review and approval of emergency plans, the rules require that the earlier approved plans must be updated and/or corrected, if needed, to ensure that they continue to comply with the applicable regulatory requirements.

Comments 003-5: If NRC determines that any of the public comments raise re-notice questions under the APA, several commenters urged the Commission to initiate an expedited rulemaking to ensure that any new rule associated with new plant licensing is completed prior to the submittal of the first COL applications. The commenters want in place as soon as possible a more efficient, less time-consuming licensing and hearing process.

NRC Response: The NRC has determined that one set of changes in response to comments, relating to revision to the LWA process in 10 CFR 50.10, require renoticing. The NRC published a supplementary proposed rule on the LWA process in October 2006.

Comment 005-17: A commenter encouraged the NRC to review those elements of the rules (e.g., Part 50, Part 52) related to financial qualifications and other issues that may be addressed in the Energy Policy Act of 2005. If changes are required to comply with the Act, it would be preferable to incorporate them into this action rather than undertaking a separate rulemaking that would delay their implementation.

NRC Response: The Commission disagrees with the commenter's suggestion. There are many ongoing NRC activities addressing compliance with the Energy Policy Act of 2005, most of which are unrelated to the Part 52 rulemaking. It would be disruptive of the regulatory process to incorporate them into his rulemaking. However, the Commission agrees that regulatory language in the Part 52 rulemaking should be consistent with the Energy Policy Act. The Commission has ensured that provisions in the final rule are consistent with the Energy Policy Act of 2005.

Comments 006-6 and 010-2: Two commenters argued that if the proposed rule is adopted in its present form, it would represent a retreat from the NRC quest for finality in the early site permit, design certification, and combined license processes. One commenter (010), believed that some of the regulatory changes and their timing will erode predictability in the regulatory process and will decrease effectiveness, and cited, as an example, changes which eliminate the requirement for the Commission to treat as resolved those issues previously resolved in an Early Site Permit proceeding.

NRC Response: The NRC's final rule contains changes which address, to some extent, the commenters' concerns. However, the NRC believes that the final rule is consistent with the Commission's original vision for Part 52, but reflects lessons learned from the review of four

design certification applications, three early site permit applications, and the development to date of pre-application guidance for combined licenses, as well as being consistent with applicable law.

Comments 009-4, 014-1, 014-2, 015-1, 016-1, and 017-1: Commenters endorsed the NEI letters submitted to the NRC regarding the proposed rule. Commenters expressed their full support for the NEI recommendations contained within the letters, and stated the importance of the NEI's recommendations and amendments to the efficiency and predictability of their industries. The commenters stated their support of the coordinated efforts by the NRC staff and the industry to ensure an efficient and effective licensing process. One of the commenters also strongly supports the NEI comments related to the timing of final regulations.

NRC Response: No response necessary.

Comment 018-1: The commenter commended NRC's efforts in preparing this proposed rule that enhances its effectiveness and efficiency in implementing its licensing and approval processes. The commenter supported the NRC's approach of addressing the applicability of various requirements to each of the licensing processes (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license).

NRC Response: No response necessary.

6 Availability of Documents

No comments received.

7 Agreement State Compatibility

No comments received.

8 Plain Language

No comments received.

9 Voluntary Consensus Standards

No comments received.

10 Environmental Impact-Categorical Exclusion

No comments received.

11 Paperwork Reduction Act Statement

No comments received.

12 Regulatory Analysis

No comments received.

13 Regulatory Flexibility Certification

No comments received.

14 Backfit Analysis

No comments received.

Appendix A: Comment Numbers, Commenter Names and Organizations, and Issues Commented On

| Comment Number | ADAMS Accession No. | Commenter Name | Organization | Issue Outline Sections |
|---------------------------|---------------------|--------------------|---|--|
| 001 | ML061310166 | Schaefer, Kurt | A&K Nuclear Licensing Inc. | 5.3.3, 16 |
| 002 | ML061370648 | Heymer, Adrian | Nuclear Energy Institute | 4.9 |
| 003 | ML061460167 | Heymer, Adrian | Nuclear Energy Institute | 4.12, 4.12, 5.6, 5.3.4, 16 |
| 004 | ML061510471 | Heymer, Adrian | Nuclear Energy Institute | 5.4.2 |
| 005 ^a | ML061510474 | Gardner, Ronnie | Areva NP | 4.13, 4.15, 5.3, 5.6, 5.13, 5.3.3, 5.3.6, 5.4.3, 5.4.5, 5.4.6, 5.4.7, 5.4.9, 5.4.30, 16 |
| 006 ^{a, b, c, d} | ML061510475 | Sterdis, Andrea | Westinghouse Electric Company | 3, 4.14, 5.10, 5.3.2, 5.3.3, 5.3.4, 5.4.7, 16 |
| 007 | ML061580572 | Heymer, Adrian | Nuclear Energy Institute | 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13, 4.14, 4.15, 5.3, 5.4, 5.6, 5.8, 5.10, 5.13, 5.16, 5.17, 5.20, 5.22, 5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5, 5.3.6, 5.4.2, 5.4.5, 5.4.6, 5.4.7, 5.4.8, 5.4.9, 5.4.10, 5.4.12, 5.4.15, 5.4.19, 5.4.21, 5.4.22, 16 |
| 008 | ML061510482 | Martinez, R. | | 4.9, 5.13, 7, 16 |
| 009 ^{a, b, c, d} | ML061510484 | McCabe, Brian | Progress Energy | 2, 4.14, 5.3.2, 5.3.3 |
| 010 ^{a, b, c, d} | ML061510487 | Keuter, Dan | Entergy Nuclear Inc. | 4.9, 16 |
| 011 | ML061510489 | Neenan, Frances | | 4.9, 5.13, 5.3.2, 5.3.4 |
| 012 ^a | ML061530400 | Grecheck, Eugene | Dominion Nuclear | 4.9, 5.13, 5.3.2, 5.3.4 |
| 013 ^{a, b, c, d} | ML061560023 | Stall, J.A. | Florida Power and Light Company | 4.8, 4.12, 5.6, 5.3.2, 5.3.3, 5.3.4, 5.4.2 |
| 014 ^a | ML061590278 | Kray, Marilyn | NuStart Energy | 2, 5.3, 16 |
| 015 ^a | ML061590292 | Kray, Marilyn | Exelon Generation | 2, 5.3 |
| 016 ^a | ML061590086 | Miller, J.A. | Southern Nuclear Operating Company, Inc. | 2, 5.3, 5.3.3 |
| 017 ^a | ML061590087 | Krich, R.M | UniStar Nuclear | 2 |
| 018 | ML061590088 | Norton Miller, Ann | United States Environmental Protection Agency | 16 |
| 019 | ML061640247 | Quinn, Vanessa E. | United States Department of Homeland Security | N/A |

^a Commenters 006, 009, 010, 012, and 013 also fully endorsed and supported NEI's comments submitted on May 16, 2006. Therefore, all of these commenters are included in each of NEI's May 16, 2006 comments (comment number 002).

^b Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI's comments submitted on May 25, 2006. Therefore, all of

these commenters are included in each of NEI's May 25, 2006 comments (comment number 003).

- ^c Commenters 006, 009, 010, and 013 also fully endorsed and supported NEI's comments submitted on May 25, 2006. Therefore, all of these commenters are included in each of NEI's May 25, 2006 comments (comment number 004).
- ^d Commenters 005, 006, 009, 010, 012, 013, 014, 015, 016, and 017 all fully endorsed and supported the Nuclear Energy Institute's (NEI's) comments of May 30, 2006. Therefore, all of these commenters are included in each of NEI's May 30, 2006 comments (comment number 007).