

## RULEMAKING ISSUE NOTATION VOTE

May 8, 2002

SECY-02-0077

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations

SUBJECT: PROPOSED RULE TO UPDATE 10 CFR PART 52, "EARLY SITE PERMITS, STANDARD DESIGN CERTIFICATIONS, AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS"

PURPOSE:

To request Commission approval to publish in the *Federal Register* a proposed revision to the requirements in Part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 52), "Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants," and proposed revisions to other related sections of the regulations in Title 10.

SUMMARY:

This rulemaking to enhance 10 CFR Part 52 is based on lessons learned during previous design certification reviews and on discussions with stakeholders about the early site permit, design certification, and combined license review processes. The rulemaking also makes conforming changes to related sections of the regulations and addresses comments received on the draft rule language that was made available for comment on the NRC's rulemaking Web site on September 27, 2001.

The NRC staff is proposing some significant changes which are discussed in Section III of the attached *Federal Register* notice. Five issues related to this rulemaking are addressed below. The first issue relates to the Commission's direction in 1994 to impose requirements on future licensees to maintain, update, and use a probabilistic risk assessment for the life of a nuclear facility. The second issue relates to a nuclear industry proposal in 1999 to revise the change criteria in the design certification rules. The third issue relates to emergency preparedness requirements for a combined license. The fourth issue involves the status of two petitions submitted by the Nuclear Energy Institute (NEI) to revise the requirements in 10 CFR Part 52. The fifth issue involves conforming changes to clarify the applicability of 10 CFR Part 21.

CONTACT:

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The NRC staff recommends that the Commission approve the attached notice of proposed rulemaking for publication and certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities. This certification is needed to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

#### BACKGROUND:

On December 4, 1998, the NRC staff submitted SECY-98-282, "Part 52 Rulemaking Plan," to implement part of Direction Setting Issue #10, "Reactor Licensing for Future Applicants." This rulemaking plan to enhance 10 CFR Part 52 was based on lessons learned during the previous design certification reviews and on discussions with nuclear industry representatives about the 10 CFR Part 52 licensing processes. In a January 14, 1999, staff requirements memorandum (SRM), the Commission approved the rulemaking plan and directed the staff to seek involvement of stakeholders before proposing the rule to the Commission. A notice of the rulemaking plan was added to the NRC's rulemaking Web site on June 16, 1999. On September 3, 1999, letters were sent to 10 external stakeholders informing them of this rulemaking and soliciting comments. NEI submitted comments on April 3, 2001, and the NRC staff considered those comments in developing this proposed rule.

On August 2, 2001, the Commission issued an SRM following a briefing on risk-informing special treatment requirements and stated that the NRC staff should engage stakeholders early in the process of rulemaking for 10 CFR Part 52. The Commission also stated that the staff could share draft rule language with all stakeholders in advance of the proposed rule. In response to this SRM, the staff posted draft rule language on the rulemaking Web site and published notification of the availability of the draft rule language in the *Federal Register* on September 27, 2001. Subsequently, General Electric, Entergy, NEI, Westinghouse Electric, and Exelon Generation submitted comments on the draft language. The staff considered their comments in the development of this proposed rule and posted revised draft rule language on the NRC's rulemaking Web site on February 28, 2002.

#### DISCUSSION:

This proposed rule revises 10 CFR Part 52 and related sections of 10 CFR Parts 2, 20, 21, 50, 51, 72, 73, 140, and 170. In a significant change to the structure of 10 CFR Part 52, the NRC staff is proposing that each licensing process in 10 CFR Part 52 have its own subpart. The purpose of this change is for consistency with other parts and to show that each of the licensing processes has equal standing. The staff also proposes to retitle 10 CFR Part 52 as "Additional Licensing Processes for Nuclear Power Plants," because the licensing processes in 10 CFR Part 52 are in addition to the two-step process in 10 CFR Part 50 and the license renewal process in 10 CFR Part 54. Several subparts will be reserved for future licensing processes. Other changes address issues identified during the design certification reviews and during discussions with external stakeholders on the 10 CFR Part 52 licensing processes. The reasons for all of the substantive changes are described in Section III of the attached *Federal Register* notice.

The NRC staff also considered whether it should address the renewal of combined licenses in this rulemaking and has determined that this issue should be deferred to a future rulemaking after the staff has gained some experience with the combined license process under

10 CFR Part 52. The staff believes that lessons learned during the licensing process under 10 CFR Part 52 could be directly applicable to the combined license renewal process. For this reason, the staff has not proposed any changes related to renewal of a combined license in this rulemaking.

### Probabilistic Risk Assessment

Current Subpart B to 10 CFR Part 52 sets out the requirements and procedures applicable to Commission issuance of rules granting certification of nuclear power plant designs. Section 52.47 sets forth the requirements for the contents of design certification applications. Paragraph 52.47(a)(1)(v) requires an application for design certification to contain a design-specific probabilistic risk assessment (PRA).

Subpart C to 10 CFR Part 52 sets out the requirements and procedures applicable to Commission issuance of combined licenses for nuclear power facilities. Section 52.79 sets forth the requirements for the contents of combined license applications. Paragraph 52.79(b) sets out the technically relevant information required of applicants for combined licenses and requires an application that does not reference a certified design to comply with the requirements of § 52.47(a)(1)(v) to provide a design-specific PRA.

One of the proposed changes to 10 CFR Part 52 is a revision to the current § 52.79(b) (proposed § 52.211(b)) to state that a combined license application that does reference a certified design must include a plant-specific PRA based on the design-specific PRA that is updated to account for site-specific design information and any design changes. In addition, the proposed rule revises § 52.211(b)(2) to explicitly state that an application not referencing a certified design must contain a plant-specific PRA, rather than referencing the requirement in § 52.47(a)(1)(v). The NRC staff proposes no further changes or additions to PRA requirements in 10 CFR Part 52.

In SECY-94-182, "Probabilistic Risk Assessment (PRA) Beyond Design Certification," dated July 11, 1994, the NRC staff provided the Commission with its proposal for using PRAs after the NRC issues a design certification in accordance with 10 CFR Part 52 and asked the Commission for guidance on this subject. The staff concluded that there were significant benefits to maintaining a living PRA and that a living PRA, properly used during the advanced design life cycle (design, construction, and operation), could (1) improve safety by providing a tool to separate the more important safety aspects from the less important; (2) aid in determining priorities and resource allocations; and (3) estimate the sources and magnitude of risk. The staff proposed that licensees be required to maintain, update, and use a PRA for the life of the facility and outlined three options for establishing this requirement. In an SRM dated July 27, 1994, the Commission approved Option 2, development of a generic "operational rule" applicable to all applicants for and holders of combined licenses. The NRC staff deferred development of this rule because, until recently, it was considered a low priority. In 2000, this action was subsumed into the Part 52 rulemaking.

External stakeholders raised this issue again during a February 16, 2001, meeting on 10 CFR Part 52 and, in a November 13, 2001, letter, NEI provided comments on the draft proposed rule language. NEI stated in comment 11.1b that . . . "no such requirement is appropriate in Part 52. SOC [statements of consideration] and guidance could identify the expectation that future licensees will update and maintain their plant-specific PRAs."

Since 1994, the NRC has made significant progress toward risk-informed regulation. The NRC staff has implemented the revised reactor oversight process and the revised maintenance rule, including the requirement that licensees assess and manage the increase in risk from proposed maintenance activities. Industry PRA standards and a peer review process have been developed. Licensees have substantially improved their PRAs to take advantage of risk-informed regulation. The above events have combined to provide (1) improved safety by focusing attention on the more important safety aspects; (2) improved methods for determining priorities and allocating resources; and (3) improved ability to estimate the sources and magnitude of risk. Therefore, the staff does not believe that it is necessary in today's regulatory environment to impose requirements that licensees maintain, update, and use a PRA for the life of the facility. If, in the future, the staff considers recommending that the Commission impose a living PRA requirement on licensees of operating plants, then the staff will consider a similar requirement for future applicants. For these reasons, the staff proposes not to add a living PRA requirement to 10 CFR Part 52.

#### 10 CFR 50.59 Change Criteria

In SECY-99-130, "Final Rule – Revisions to Requirements of 10 CFR Parts 50 and 72 Concerning Changes, Tests, and Experiments," dated May 12, 1999, the NRC staff requested the Commission's approval to publish a final rule revising 10 CFR 50.59 and related requirements. Section 50.59 concerns licensees' authority to make changes to their facilities and procedures or to conduct tests and experiments without prior NRC approval. The revisions to § 50.59 were published in the *Federal Register* on October 4, 1999 (64 FR 53582). During the preparation of the § 50.59 rulemaking, nuclear industry commenters proposed that each of the three design certification rules (Appendices A, B, and C) in 10 CFR Part 52 be amended to incorporate the revised change criteria in § 50.59. SECY-99-054, "Plans for Final Rule – Revisions to 10 CFR Parts 50, 52, and 72: Requirements Concerning Changes, Tests, and Experiments," dated February 22, 1999, included draft final rule revisions to the design certification rules for the Advanced Boiling Water Reactor and System 80+ designs. However, in SECY-99-130, the staff noted that a rulemaking was planned to update 10 CFR Part 52 for areas of improvement. The staff stated that it would consider the final revisions to § 50.59 during the rulemaking to update 10 CFR Part 52 and, therefore, would defer incorporating the revised § 50.59 criteria into the design certification rules.

In developing the proposed rule changes to 10 CFR Part 52, the NRC staff posted draft rule language on the NRC's rulemaking Web site on September 27, 2001, that included revisions to Appendices A, B, and C to incorporate the revised § 50.59 change criteria. The staff believed it would be beneficial to have a change process for Tier 2 information that conforms with the § 50.59 process for nuclear power plant licensees. The staff has incorporated the new criteria into the § 50.59-like change process in each of the three design certification rules in Appendices A, B and C of 10 CFR Part 52. In addition, the staff has prepared, after consulting with the Office of the General Counsel (OGC), a proposed change to current § 52.63(a)(1) (proposed § 52.127(a)(1)), which would permit the Commission to modify design certification rules by notice and comment rulemaking by adding a new criterion to that allows changes that reduce unnecessary regulatory burden and maintain protection to public health and safety and the common defense and security. The purpose of the proposed change is two-fold: (1) to allow the Commission to adopt in the final 10 CFR Part 52 rulemaking the proposed new criteria

for the § 50.59-like change process into the three design certification rules<sup>1</sup>; and (2) in the future to allow the Commission to modify design certification rules to reduce unnecessary regulatory burden, so long as protection to public health and safety and common defense and security are maintained.

### Emergency Preparedness

Issues regarding the review and verification of emergency preparedness for nuclear power plants have been the subject of much correspondence between the NRC staff and Commission from 1989 to the present. The staff reviewed the historical record regarding the requirements for emergency preparedness exercises for combined license holders to evaluate whether proposed changes to 10 CFR Part 52 were necessary at this time. The staff has confirmed that the full-participation exercise does not need to be performed before issuance of a combined license. The staff has also determined that the requirements in 10 CFR Part 52 related to emergency preparedness exercises do not need to be revised at this time. However, the staff has determined that the emergency planning regulations in 10 CFR Part 50 may need to be amended in order to incorporate the licensing processes that now exist in 10 CFR Part 52 for early site permits and combined licenses. In light of its recent review, the staff now plans to include conforming administrative changes to 10 CFR Part 50 Appendix E with the upcoming rulemaking that was outlined in SECY-01-0131, "Revision of Appendix E, Section IV.F.2 to 10 CFR Part 50, Concerning Clarification of Emergency Preparedness Exercise Participation Requirements of Co-Located Licensees." The following discussion summarizes the staff's review of the history of this issue.

In a February 17, 1989, memorandum from the Executive Director for Operations, the staff alerted the Commission to an issue associated with emergency planning requirements as they related to the combined license process in Subpart C of 10 CFR Part 52. The staff stated that 10 CFR Part 52 would require that complete emergency plans be approved and exercised before the combined license was issued. In accordance with 10 CFR 52.97(a), the Commission must find that the applicable requirements of 10 CFR 50.47, among others, have been met before issuance of a combined license. It was stated in the memorandum that an initial exercise would be held before issuance of the combined license and exercises would be held every two years thereafter until operation. In a June 29, 1989, memorandum, the staff indicated to the Commission that although a pre-licensing exercise could be developed, some aspects of the plans would be difficult to demonstrate prior to construction of the facility (e.g. the control room and emergency response facilities). Additionally, if portions of the plans were exercised for the first time in post-licensing tests, the results might be subject to an opportunity for hearing relatively late in the process. On September 11, 1989, the Commission (COMKC-89-9, "Review of the Emergency Preparedness Regulations (Memorandum from the Executive Director for Operations to the Commissioners, dated June 29, 1989)) requested that the staff update 10 CFR Part 50 emergency planning requirements to better reflect the goals of 10 CFR Part 52 with respect to, in part, review of the safety basis of the regulatory requirement for a full participation exercise with the objective of determining whether exercise timing and frequency can be detached from the authorization to operate under a combined license or the

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<sup>1</sup>OGC has advised that the current language of 10 CFR 52.63(a)(1) appears to restrict the agency from modifying the § 50.59-like change process in the current design certification rules to incorporate the new § 50.59 criteria.

permissible timing of the exercise extended, and address the extent to which exercise results would be litigated in NRC hearings under 10 CFR Part 52.

In 1992, the Energy Policy Act of 1992 was enacted. Among other things, the new legislation specified that inspections, tests, analyses, and acceptance criteria (ITAAC) in combined licenses must include those applicable to emergency planning. The new legislation also allowed interim plant operation prior to completion of a hearing on whether the acceptance criteria had been met. Therefore, such a hearing would not delay operation of the plant if the Commission were to find, after consideration of petitioners' prima facie showing, that there is reasonable assurance of adequate protection of public health and safety.

Considering the language in this new legislation and the difficulties with the staff's 1989 position requiring that an initial exercise be held before issuance of a combined license, the NRC staff developed SECY-95-090, "Emergency Planning Under 10 CFR Part 52," dated April 11, 1995. SECY-95-090 was developed to inform the Commission of the staff's views on how emergency planning requirements, including exercise requirements, would be addressed at each phase of nuclear power plant licensing under 10 CFR Part 52. The staff stated that an application for a combined license must include proposed ITAAC, including those applicable to emergency preparedness (current §52.79(c)). These ITAAC are to be those that are necessary and sufficient to demonstrate compliance with 10 CFR 50.47(b), or any acceptable alternatives as provided for in 10 CFR 50.47(c). The staff recognized that a reasonable assurance finding would have to be made before plant features required for emergency response were completed. However, the staff noted that the establishment of and the requirement to meet these ITAAC in the combined license would enable the NRC, in consultation with the Federal Emergency Management Agency (FEMA), to make a predictive regulatory finding of reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Because the initial full-participation exercise required by Section IV.F.2.a<sup>2</sup> of Appendix E to 10 CFR Part 50 would be a combined license ITAAC, it would have to be conducted along with other inspections, tests, and analyses, and meet the acceptance criteria before fuel is loaded. The ITAAC for this initial exercise would necessarily be the last emergency preparedness ITAAC completed and it would be necessary for both FEMA and NRC to evaluate that exercise. In that all other ITAAC related to both onsite and offsite emergency preparedness would have been met prior to the conduct of the full participation exercise, all the necessary onsite and offsite plans, procedures, personnel, equipment, etc. would be in place to allow for the testing

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<sup>2</sup>Section IV.F.2.a of Appendix E to 10 CFR Part 50 requires a full participation exercise to be conducted within two years before the issuance of the first operating license for full power (one authorizing operation above 5% of rated power) of the first reactor and shall include participation by each State and local government within the plume exposure pathway Emergency Planning Zone (EPZ) and each state within the ingestion exposure pathway EPZ. If the full participation exercise is conducted more than one year prior to issuance of an operating license for full power, an exercise which tests the licensee's onsite emergency plans shall be conducted within one year before the issuance of an operating license for full power. This exercise need not have State or local government participation.

of both the licensee's and State and local emergency response plans<sup>3</sup> as required by Appendix E. The periodic exercises required by 10 CFR 50.47(b)(14) and 10 CFR Part 50 Appendix E, Section IV.F.2 would be conducted after the initial full-participation exercise, as part of the licensee's emergency plan.

#### Industry Petitions on 10 CFR Part 52

In two separate submittals on July 18, 2001, NEI petitioned the NRC for changes to 10 CFR Part 52 early site permit and combined license requirements. The first petition (Docket No. PRM 52-1) sought to modify 10 CFR Part 52 to avoid duplicative NRC reviews of valid, existing site and facility information that was previously approved by the NRC and subject to public hearing. The petition asked that the proposed 10 CFR Part 52 changes be merged into this 10 CFR Part 52 update rulemaking.

The second petition (Docket No. PRM-52-2) requested that requirements to consider alternate sites in early site permit applications, and NRC reviews thereof, be eliminated. The petitioner also asked NRC to revise 10 CFR Part 51 to reflect that NRC review of alternatives under the National Environmental Policy Act need not, and thus should not, consider need for power, alternate sources, or alternate sites. The petitioner stated that these matters are best determined by State and local governments, the applicant, and the marketplace. The petitioner requested that the proposed 10 CFR Part 52 changes be merged into this 10 CFR Part 52 update rulemaking. The petitioner also asked that the Commission initiate a rulemaking to amend 10 CFR Part 51 and related provisions in 10 CFR Parts 2 and 50.

The two NEI petitions were published in the *Federal Register* for comment on September 24, 2001. Nine comments were received on the PRM 52-1 and eleven comments were received on PRM 52-2.

The NRC staff is currently preparing its recommendations on these two petitions for submittal to the Commission. Because the staff has not completed drafting its recommendations, the attached proposed rule does not address the petitions. The staff concluded that it would not be prudent to delay the 10 CFR Part 52 proposed rulemaking further until completion of action on these two petitions. The staff expects to submit its recommendations on the petitions to the Commission by September 2002.

#### 10 CFR Part 21

The proposed rule includes a number of conforming changes to clarify the applicability of 10 CFR Part 21 to individuals, corporations, partnerships, or other entities doing business within the United States, and directors and responsible officers of such organizations, that hold a permit or license under 10 CFR Part 52. These conforming changes would correct an oversight when the Commission first adopted 10 CFR Part 52, to ensure that the requirements in

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<sup>3</sup>10 CFR 52.79(d) and 50.47(c)(1) allow for licensee plans for situations where State or local governments decline or fail to participate in offsite radiological emergency planning and preparedness. In determining adequacy of such a plan, the NRC will recognize that, in an actual emergency, State and local government officials will take actions to protect the health and safety of the public.

10 CFR Part 21 apply to applicants for and holders of combined licenses, manufacturing licenses, and duplicate design licenses, and suppliers of basic components to such holders.

For applicants and holders of an early site permit, and the applicant/vendor of a design certification rule, the NRC staff proposes a different approach. The staff believes that 10 CFR Part 21 should apply only after an early site permit has been referenced by the holder in a license application, and only after a design certification rule has been first referenced in a license application. Although OGC has advised the staff that there is legal authority to apply 10 CFR Part 21 to a design certification applicant/vendor upon Commission adoption of a design certification rule, and (with appropriate rule changes redefining the term "supplies" in the context of an early site permit) to an early site permit holder once an early site permit is issued, the staff recommends a different course. As explained in more detail in the *Federal Register* notice, the staff believes that there is no reasonable concern about safety unless either the early site permit or design certification is referenced in a license application. Moreover, requiring the early site permit holder to comply with 10 CFR Part 21 notification requirements is inconsistent with the staff's proposal that, with the exception of emergency preparedness information, the early site permit holder should not have to update the information for the permit (see discussion in section III.A.8 of the *Federal Register* notice). The staff has included a question in section IV of the *Federal Register* notice seeking public comments on this matter.

#### RESOURCES:

The FY 2002 budget includes a total of 1.2 FTE to finalize, publish, issue, and implement the proposed rulemaking and start the final rulemaking. No resources were originally included in the FY 2003 budget for this effort because the final rule was to have been completed in FY 2002. However, extending the completion of the final rule to late in 2002 (FY 2003) requires that approximately 0.3 FTE will be reprogrammed in FY 2003 to complete the final rule, including resolution of public comments.

#### COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Chief Financial Officer concurs in the proposed changes to 10 CFR Part 170. The Office of the Chief Financial Officer has also reviewed this paper for resource implications and has no objections.

The staff briefed the Advisory Committee on Reactor Safeguards (ACRS) on the draft proposed rule language for 10 CFR Part 52 on November 8, 2001. In a letter dated November 14, 2001, the ACRS stated that it planned to review the proposed final version of 10 CFR Part 52 following the reconciliation of public comments. The Committee To Review Generic Requirements will also review the proposed final version of 10 CFR Part 52 following the reconciliation of public comments.

#### RECOMMENDATION:

That the Commission:

1. *Approve* the notice of proposed rulemaking for publication (Attachment).

2. *Certify* that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities in order to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. *Note* –
  - a. The rulemaking will be published in the *Federal Register* with a 75-day public comment period.
  - b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.
  - c. The appropriate congressional committees will be informed.
  - d. The proposed rule does not impose requirements that future licensees maintain, update, and use a PRA for the life of the facility.
  - e. The NRC staff has determined that the emergency planning regulations in 10 CFR Part 50 may need to be amended in order to incorporate the licensing concepts that now exist in 10 CFR Part 52 for early site permits and combined licenses and that the NRC staff plans to include conforming administrative changes to Appendix E of 10 CFR Part 50 with the upcoming rulemaking that was outlined in SECY-01-0131.

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William D. Travers  
Executive Director  
for Operations

Attachment: *Federal Register* Notice

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 20, 21, 50, 51, 52, 72, 73, 140, and 170

RIN 3150 - AG24

Changes to Requirements for Early Site Permits, Standard Design Certifications, and  
Combined Licenses for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is proposing to amend its requirements for early site permits, standard design certifications, combined licenses for nuclear power plants, and for other licensing processes in 10 CFR Part 52. The amendments are based on the NRC staff's experience with the previous design certification reviews and on discussions with stakeholders about the early site permit (ESP), design certification, and combined license (COL) processes. This action is expected to improve the effectiveness of the licensing processes in 10 CFR Part 52 for future applicants.

DATES: Submit comments by (insert date 75 days after publication in the *Federal Register*). Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Rulemakings and Adjudications Staff.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking Web site at <http://ruleforum.llnl.gov>. This site provides the capability to upload comments as files (any format), if your Web browser supports that function. For information about the interactive rulemaking Web site, contact Ms. Carol Gallagher at (301) 415-5905 (email:cag@nrc.gov).

The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm.html>. If you do not have access to ADAMS or if there are

problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr@nrc.gov](mailto:pdr@nrc.gov).

FOR FURTHER INFORMATION CONTACT: Jerry N. Wilson, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone (301) 415-3145, email [jnw@nrc.gov](mailto:jnw@nrc.gov); or Nanette V. Gilles, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone (301) 415-1180, email [nvg@nrc.gov](mailto:nvg@nrc.gov).

SUPPLEMENTARY INFORMATION:

- I. Background.
- II. Reorganization of 10 CFR Part 52.
- III. Discussion of Substantive Changes.
  - A. 10 CFR Part 52, Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants.
    - A.1 General Provisions.
    - A.2 Early Site Permits.
    - A.3 Early Site Reviews.
    - A.4 Standard Design Certifications.

- A.5 Design Certification Backfit Requirements.
- A.6 Standard Design Approvals.
- A.7 Combined Licenses.
- A.8 Referencing an Early Site Permit.
- A.9 Testing Requirements for Advanced Reactors.
- A.10 Probabilistic Risk Assessments.
- A.11 Resolution of ITAAC.
- A.12 Commission Finding on Acceptance Criteria.
- A.13 Duration of a Combined License.
- A.14 Combined License Change Process.
- A.15 Design Certifications for ABWR, System 80+, and AP600.
- B. 10 CFR Part 2, Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders.
- C. 10 CFR Part 20, Standards for Protection Against Radiation.
- D. 10 CFR Part 21, Reporting of Defects and Noncompliance.
- E. 10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities.
- F. 10 CFR Part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.
- G. 10 CFR Part 72, Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste.
- H. 10 CFR Part 73, Physical Protection of Plants and Materials.
- I. 10 CFR Part 140, Financial Protection Requirements and Indemnity Agreements.
- J. 10 CFR Part 170, Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended.
- IV. Specific Requests for Comments.

- V. Availability of Documents.
- VI. Plain Language.
- VII. Voluntary Consensus Standards.
- VIII. Environmental Impact—Categorical Exclusion.
- IX. Paperwork Reduction Act Statement.
- X. Public Protection Notification
- XI. Regulatory Analysis.
- XII. Regulatory Flexibility Certification.
- XIII. Backfit Analysis.

#### I. Background

The Commission promulgated 10 CFR Part 52 on April 18, 1989 (54 FR 15386), to reform the licensing process for future nuclear power plant applicants. The rule added alternative licensing processes in 10 CFR Part 52 for early site permits, standard design certifications, and combined licenses. These were additions to the two-step licensing process that already existed in 10 CFR Part 50. The processes in 10 CFR Part 52 resolve safety and environmental issues early in licensing proceedings and are intended to enhance the safety and reliability of nuclear power plants through standardization. The rule also moved the licensing processes in Appendices M, N, O, and Q of 10 CFR Part 50 to 10 CFR Part 52. Subsequently, the NRC certified three nuclear plant designs under Subpart B of 10 CFR Part 52—the U.S. Advanced Boiling Water Reactor (ABWR) (62 FR 25827, May 12, 1997), System 80+ (62 FR 27867, May 21, 1997), and AP600 (64 FR 72015, December 23, 1999) designs—and codified these designs in Appendices A, B, and C of 10 CFR Part 52, respectively.

The NRC had planned to update 10 CFR Part 52 after using the design certification process for these three certified standard plant designs. In addition, discussions with stakeholders at public meetings and comments on SECY-00-0092, “Combined License Review

Process,” dated April 20, 2000, identified licensing issues associated with Subparts A and C of 10 CFR Part 52. As a result, the NRC initiated this proposed rulemaking to (1) clarify and/or correct 10 CFR Parts 2, 20, 21, 50, 51, 52 (including Appendices A, B, and C), 72, 73, 140, and 170; (2) update 10 CFR Part 52; and (3) incorporate stakeholder comments.

This rulemaking action began with the issuance of SECY-98-282, “Part 52 Rulemaking Plan,” on December 4, 1998. The Commission issued a staff requirements memorandum on January 14, 1999, approving the NRC staff’s plan for revising 10 CFR Part 52. A notice of the rulemaking plan was added to the NRC’s rulemaking Web site on June 16, 1999. On September 3, 1999, letters were sent to 10 external stakeholders alerting them to this proposed rulemaking. In addition, the NRC staff held three public meetings with interested stakeholders on the 10 CFR Part 52 rulemaking on December 14, 2000, February 16, 2001, and March 7, 2001. Following those meetings, on April 3, 2001, the Nuclear Energy Institute (NEI) submitted comments on issues discussed during the meetings.

On September 27, 2001, the NRC staff posted draft rule language for 10 CFR Part 52 on the NRC’s rulemaking Web site. The NRC received comments on the draft rule language in November 2001, from General Electric, Entergy, NEI, Westinghouse Electric, and Exelon Generation. The NRC staff has considered these comments in the development of this proposed rule and posted revised draft rule language for 10 CFR Part 52 on the NRC’s rulemaking Web site on February 28, 2002.

## II. Reorganization of 10 CFR Part 52

The NRC is proposing to reorganize 10 CFR Part 52 to establish a separate subpart for each of the seven licensing processes currently described in 10 CFR Part 52 (early site permits, early site reviews, standard design certification, standard design approvals, combined licenses, manufacturing licenses, and duplicate design licenses). The purpose of this reorganization is to clarify that each licensing process has equal standing. In addition, several subparts would be

reserved for future licensing processes. No substantive changes are intended by the incorporation of current Appendices M, N, O, and Q into the new subparts in 10 CFR Part 52.

The NRC is also proposing to retitle 10 CFR Part 52 as “Additional Licensing Processes for Nuclear Power Plants,” to clarify that the licensing processes in 10 CFR Part 52 are in addition to and supplement the two-step licensing process in 10 CFR Part 50 and the license renewal process in 10 CFR Part 54, and are not limited to the early site permit, standard design certification, and combined license processes as the current title implies.

The proposed rule would amend § 52.1 to clarify that all seven licensing processes are within the scope of 10 CFR Part 52. Sections within current Appendices M, N, O, and Q would also become new sections of the revised part. In addition, the proposed rule would reserve subparts for future licensing processes. In doing so, the NRC hopes to convey that 10 CFR Part 52 is the preferred location in 10 CFR for nuclear power plant licensing processes.

The proposed rule would amend § 52.19, the current § 52.49 (proposed § 52.111), and the current § 52.83 (proposed § 52.215) to provide a standard format in Subparts A, D, and G. This standard format would set forth the standards for review of applications and the applicability of NRC requirements in a consistent manner in each of these subparts. The references to the Part 170 fee requirements would be moved to be included in the sections on filing of applications. This reorganization of 10 CFR Part 52 will make the subparts on early site permits and standard design certifications consistent with the existing arrangement in the subpart for combined licenses.

The proposed rule would also move the requirement on duration of a combined license that is currently located in § 52.83, “Applicability of part 50 provisions,” to paragraph (e) of proposed § 52.227, “Issuance of combined licenses.”

The Commission has prepared the following table that cross-references the new proposed provisions in 10 CFR Part 52 to the superseded provisions of 10 CFR Part 52.

Table 1. Cross-References Between New and Old 10 CFR Part 52

<u>New section</u>	<u>Old section</u>
<i>General Provisions</i>	
52.1	52.1
52.3	52.3
52.5	52.5
52.8	52.8
None	52.9
<i>Subpart A - Early Site Permits</i>	
52.11	52.11
52.13	52.13
52.15	52.15
52.17	52.17
52.18	52.18
52.19	52.19
52.21	52.21
52.23	52.23
52.24	52.24
52.25	52.25
52.27	52.27
52.29	52.29
52.31	52.31
52.33	52.33
52.35	52.35
52.37	52.37
52.39	52.39
<i>Subpart B - Early Site Reviews</i>	
52.41	App. Q, Introduction
52.43(a)	App. Q, Paragraph 1
52.43(b)	App. Q, Paragraph 2
52.43(c)	App. Q, Paragraph 1
52.45	App. Q, Paragraph 3
52.47(a)	App. Q, Paragraph 4
52.47(b)	App. Q, Paragraph 5
52.47(c)	App. Q, Paragraph 6
52.49	App. Q, Paragraph 7
<i>Subpart D - Standard Design Certification</i>	
52.101	52.41
52.103	52.43
52.105	52.45
52.107	52.47
52.109	52.48
52.111	52.49
52.113	52.51
52.115	52.53
52.117	52.54
52.119	52.55
52.121	52.57
52.123	52.59

52.125	52.61
52.127	52.63
<i>Subpart E - Standard Design Approvals</i>	
52.131	App. O, Introduction
52.133(a)	App. O, Paragraph 1
52.133(b)	App. O, Paragraph 2
52.135	App. O, Paragraph 3
52.137	App. O, Paragraph 4
52.139(a)	App. O, Paragraph 5
52.139(b)	None
52.141(a)	App. O, Paragraph 5
52.141(b)	App. O, Paragraph 6
52.143	App. O, Paragraph 7
<i>Subpart G - Combined Licenses</i>	
52.201	52.71
52.203	52.73
52.205	52.75
52.207	52.77
52.209	52.78
52.211	52.79
52.213	52.81
52.215	52.83
52.217	52.85
52.219	52.87
52.221	52.89
52.223	52.91
52.225	52.93
52.227	52.97
52.229	52.99
52.231	52.103
<i>Subpart H - Manufacturing Licenses</i>	
52.241	App. M, Introduction
52.243(a)	N/A
52.243(b)	App. M, Paragraph 7
52.243(c)	App. M, Paragraph 9
52.243(d)	App. M, Paragraph 10
52.243(e)	App. M, Paragraph 11
52.243(f)	App. M, Paragraph 8
52.245(a)	App. M, Paragraph 2
52.245(b)	App. M, Paragraph 3
52.245(c)	App. M, Paragraph 4(b)
52.247	App. M, Paragraph 1
52.249	App. M, Paragraph 4(a)
52.253(a) & (b)	App. M, Paragraph 5
52.253(c)	App. M, Paragraph 6
52.255	N/A
52.257	App. M, Paragraph 12
<i>Subpart I - Duplicate Design Licenses</i>	
52.261	App. N, Introduction

52.263	App. N, Paragraph 1
52.265	App. N, Paragraph 2
52.265(c)	App. N, Paragraph 3
<i>Subpart M - Enforcement</i>	
52.401	52.111
52.403	52.113

### III. Discussion of Substantive Changes

A section-by-section analysis that explains the purpose and meaning of all sections in 10 CFR Part 52 will be provided in the supplementary information for the final rule. The proposed rule makes the following substantive changes:

#### *A. 10 CFR Part 52, Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants*

##### (1) General Provisions

The proposed rule would amend § 52.3 to add definitions for “modular design” and “prototype plant” to the current 10 CFR Part 52. A definition of modular design is added to explain the type of modular reactor design that the Commission intended is referring to in the second sentence of the current § 52.103(g) (proposed § 52.231(g)). This special provision for modular designs was added to 10 CFR Part 52 to facilitate the licensing of nuclear plants, such as the Modular High Temperature Gas-Cooled Reactor (MHTGR) and Power Reactor Innovative Small Module (PRISM) designs, that consisted of 3 or 4 nuclear reactors in a single power block with a shared power conversion system. During the period that the power block is under construction, the Commission could separately authorize operation for each nuclear reactor when each reactor and all of its necessary support systems were completed. In a letter dated November 13, 2001 (comment A), NEI stated that “Part 1 of the definition would need to be revised for this purpose so that it does not describe typical multi-unit sites. The NRC staff should reconsider the need to define this term at all.” The Commission disagrees with NEI’s recommendation because the term “modular design” needs to be defined to aid future use of

the current § 52.103(g) (proposed § 52.231(g)) by distinguishing the intended definition from other definitions for “modular design.” Also, currently licensed multi-unit sites are not affected by the proposed § 52.231(g) and future applicants for a single, combined license for a multi-unit site may be able to use this provision.

A definition for prototype plant is added to explain the type of nuclear reactor that the Commission intended in the current § 52.47(b) (proposed § 52.107(b)) and intends in the proposed § 52.211(b)(3). A prototype plant is a licensed nuclear reactor test facility that is similar to and representative of either the first-of-a-kind or certified nuclear plant design in all features and size, but may have additional safety features. The purpose of the prototype plant is to perform testing of new or innovative design features for the first-of-a-kind or certified, advanced nuclear plant design, as well as being used as a commercial nuclear power facility.

The proposed rule would remove §§ 52.5 and 52.9 and replace them with a new § 52.5 listing all of the licensing provisions in 10 CFR Part 50 that also apply to all of the licensing processes in 10 CFR Part 52. The purpose of this amendment is to clarify that these 10 CFR Part 50 provisions are applicable to the licensing processes that were formerly in 10 CFR Part 50 (Appendices M, N, O, and Q), as well as to the new licensing processes for early site permits, standard design certifications, and combined licenses. Although these provisions in 10 CFR Part 50 may not refer to the additional licensing processes in 10 CFR Part 52, the new § 52.5 makes it clear that a holder of or applicant for an approval, certification, permit, site report, or license issued under 10 CFR Part 52 must comply with all requirements in these provisions that are otherwise applicable to applicants or licensees under 10 CFR Part 50.

In a letter dated November 13, 2001 (comment G), NEI stated:

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

The Commission disagrees with the industry's proposal to create over 35 new general provisions that are tailored for 10 CFR Part 52 because it would be an inefficient and burdensome addition. Therefore, the Commission is proposing a new § 52.5 that would make the existing general provisions in 10 CFR Part 50 applicable to the licensing processes in 10 CFR Part 52.

## (2) Early Site Permits

The proposed rule would amend § 52.13 to state that an early site permit can also be referenced in an application for a combined license or a duplicate design license.

The proposed rule would amend § 52.17(a)(1) to state that the early site permit application should specify the range of facilities that the applicant is requesting the site to be qualified for (e.g. one, two, or three pressurized-water reactors) and the applicable site parameters for each nuclear reactor. This new language is consistent with the language in the current Appendix Q. The Commission assumes that an applicant for an early site permit does not know what type of nuclear plant it will build at the site. Therefore, the application must specify the postulated site parameters for the range of reactor types, the numbers of reactors, etc., to increase the likelihood that the site will be qualified for the actual plant or plants that the applicant decides to build. In a letter dated November 13, 2001 (comment 27), NEI stated, "The proposed change is too limited. To address the required assessment of major SSCs [structures, systems, and components] that bear on radiological consequences and all items 52.17(a)(1)(i-viii), industry recommends new § 52.17a.2." The Commission disagrees with NEI's proposal to have a separate provision for applicants who have not determined the type of plant that they plan to build at the proposed site. The Commission expects that applicants for an early site permit will not have decided on a particular type of nuclear power plant and § 52.17(a)(1) was revised to address this situation.

The proposed rule would amend §§ 52.24 and 52.39 to clarify: (1) the information that the NRC must include in the early site permit when it is issued; (2) the matters accorded finality in any subsequent NRC review and proceeding for an application referencing the early site permit; and (3) the matters that may be challenged in a contention to be resolved in an adjudication, versus those matters that may be raised in a petition to be processed in accord with 10 CFR 2.206. Section 52.211 would be amended to clarify that an application referencing an early site permit must, in addition to showing that the design of the facility falls within the site parameters specified in the early site permit, demonstrate that all terms and conditions of the early site permit have been satisfied. Section 52.24 would also be amended to provide that the early site permit must state the site parameters, as well as the “terms and conditions,” of the early site permit, rather than the “conditions and limitations” as is currently provided. No substantive change in § 52.24 is intended by the proposed amendment; the change is proposed to provide consistency with § 52.39(a)(2) and subparagraph (a)(2)(iii) of the current rule, which also refer to “site parameters” and “terms and conditions.”

Section 52.39(a) would be amended to uniformly refer to “terms and conditions” of an early site permit. Section 52.39(a)(1) would also be amended to remove the term, “requirements,” and clarify that the Commission may not change or impose new site characteristics, terms, or conditions on the early site permit, including emergency planning requirements, unless the special backfitting criteria in that subsection are satisfied. No substantive change is intended by this clarification; the Commission believes that “site characteristics, terms, and conditions” of an early site permit more accurately describe the existing scope of matters subject to the special backfitting criteria in § 52.39(a)(1).

Currently, 10 CFR Part 52 uses the various terms, “site parameters,” “postulated site parameters,” “site characteristics,” “physical characteristics,” and “the parameters specified in the early site permit” See, e.g., §§ 52.17, 52.18, 52.21, 52.47 (proposed § 52.107), § 52.79

(proposed § 52.211). In some cases, it appears that different terms are used to apply to the same concept, e.g., “site parameters,” and “postulated site parameters.” In other cases, information which would appear to constitute “site parameters” as used in the current rule is not characterized as such, e.g. § 52.17(a)(1)(i) through (viii).

To address these inconsistencies, the Commission is considering amending 10 CFR Part 52, including proposed Subparts A, D, and G, to use three terms: “site characteristics,” “site parameters,” and “design parameters,” to set forth in clear and unambiguous terms the Commission’s requirements on early site permits, design certifications, and combined licenses. “Site characteristics” to be the actual physical and demographic values for the site, e.g., the ground force acceleration of a defined earthquake, flood level, or the atmospheric dispersion value. The “design parameters” for an early site permit would include the postulated values for thermal power level, radiological effluents, and type of cooling system for the facility. “Site parameters” for a design certification would include the postulated values for floods, ground force acceleration of a postulated earthquake, and tornado wind speeds. The amendment to 10 CFR Part 52 would: (1) require the Commission to specify site parameters and design parameters when issuing early site permits; (2) require the design certification rule to specify the site parameters and design parameters for the design; (3) require a combined license applicant referencing an early site permit to demonstrate that either the design of the nuclear power plant or the site parameters and design parameters of a referenced design certification rule, fall within/meet the design and site parameters of the early site permit; and (4) require a combined license applicant referencing a design certification rule to demonstrate that the site parameters and design parameters of the design certification rule fall within/meet either: (i) the site characteristics of the site, or (ii) the site parameters and design parameters of a referenced early site permit. The Commission will consider any comments submitted in response to

question #2 in section IV in determining whether to amend 10 CFR Part 52 in the manner described above.

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

### (3) Early Site Reviews

The proposed rule would amend certain sections of the current Appendix Q to 10 CFR Part 52 (proposed §§ 52.41, 52.43, and 52.47) to clarify that an early site review can also be used in an application for a combined license or a duplicate design license.

### (4) Standard Design Certifications

The proposed rule would amend the current §§ 52.41 and 52.45 (proposed § 52.101 and § 52.105) to clarify that a certified design may be referenced in an application for a duplicate design license, as well as a combined license application, filed under Part 52.

The proposed rule would remove the requirements currently located in §§ 52.43(c), 52.45(c), and 52.47(b)(2)(ii) because the Commission has decided not to require a final design approval (FDA) as a prerequisite for certification of a standard plant design under the new Subpart D of 10 CFR Part 52. This requirement was included in 10 CFR Part 52 because, at the time of the original rulemaking, the NRC had no experience with design certification applications. By requiring an FDA as a prerequisite for certification, the NRC indicated that the

licensing processes for design certifications and FDAs were similar, even though the requirements for and finality of design certifications differ from that of FDAs. The NRC has considerable experience with design certification applications and the requirement to apply for an FDA as part of an application for design certification is no longer needed.

In a letter dated April 3, 2001 (comment 2), NEI commented “Industry prefers to retain modified provisions. We agree that an FDA should be an option but not a prerequisite. Also, deletion recommended for 52.47(b)(2)(ii).” The Commission has decided not to retain these provisions. The proposed processes in Subparts D and E allow future applicants for design certification the option to apply for an FDA for the same design information.

The proposed rule would also amend the current § 52.45(d) (proposed § 52.105(c)) to correct the reference to the filing requirements in § 50.30(a) and delete the reference to § 50.4. The applicability of the requirements in § 50.4 is set forth in the new § 52.5. No substantive change in the filing requirements is intended by this correction.

The proposed rule would amend the current § 52.47 (proposed § 52.107) to conform the statement of the requirements for acceptable inspections, tests, analyses, and acceptance criteria (ITAAC) in § 52.107 with the Atomic Energy Act (AEA) and the requirements in the current § 52.97(b) [proposed § 52.227(b)]. This clarification of the previous regulatory text, which condensed the language in § 52.79(c) and § 52.97(b), is intended to avoid any future misunderstandings.

#### (5) Design Certification Backfit Requirement

The proposed rule would amend the special backfit requirement in the current § 52.63(a)(1) (proposed § 52.127(a)(1)) to provide the Commission with the ability to make changes to the design certification rules or the certification information in the generic design control documents that reduce unnecessary regulatory burdens. Section 52.63(a)(1) currently states that the Commission may not modify, rescind, or impose new requirements on the

certification unless the change is: (1) necessary for compliance with Commission regulations applicable and in effect at the time the certification was issued, or (2) necessary to provide adequate protection of the public health and safety or common defense and security. The regulation does not appear, on its face, to permit changes to the certification which reduce unnecessary regulatory burdens, in circumstances where the change continues to maintain protection to public health and safety and common defense and security. An example of a change which may not be able to be made under the current § 52.63(a)(1) is a proposed change to the three design certification rules in Appendices A, B and C of 10 CFR Part 52, to incorporate into the Tier 2 change process the revised change criteria in 10 CFR 50.59. Section 50.59 was revised in 1999 to provide new criteria for, *inter alia*, making changes to a facility, as described in the final safety analysis report, without prior NRC approval, in order to reduce unnecessary regulatory burden (64 FR 53582, October 4, 1999).

To allow the Commission to modify the design certification rules in 10 CFR Part 52 to incorporate the revised § 50.59 change criteria, and to allow the Commission to make future changes to reduce unnecessary regulatory burden, the Commission is proposing to amend § 52.127(a)(1) to include a new provision that explicitly allows the Commission to change the design certification rules or certification information if the change provides a reduction in regulatory burden and maintains protection to public health and safety and common defense and security. Maintaining protection generally embodies the same safety principles used by the NRC in applying risk-informed decision making, e.g., ensuring that adequate protection is provided, applicable regulations are met, sufficient safety margins are maintained, defense-in-depth is maintained, and that any changes in risk are small and consistent with the Commission's Safety Goal Policy Statement (refer to NRC's Regulatory Guide 1.174). Changes to the design certification rules must be accomplished through rulemaking, with opportunity for public comment. Once a design certification rule is changed through

rulemaking, under proposed § 52.127(a)(2) the provisions would apply to all future applications referencing the design certification rule as well as all current plants referencing the design certification, unless the change has been rendered “technically irrelevant” though other action taken under paragraphs (a)(3) or (b)(1) of § 52.127. Thus, standardization is maintained by ensuring that any changes to a design certification rule intended to reduce regulatory burden are imposed upon all nuclear power plants referencing the design certification rule.

In a letter dated November 13, 2001, NEI stated:

Furthermore, we do not think it is necessary to modify 10 CFR 52.63(a)(1) in order to make conforming, administrative or similar changes to the DCRs, such as those needed to conform the DCRs to the revised 10 CFR 50.59. Nor do we think the Commission intended the DCR backfit provisions to inhibit these types of changes. Rather, we believe 10 CFR 52.63(a)(1) is intended to apply to changes in the standard design approved via the DCR. We recommend the Commission clarify this intent and provide guidance to the NRC staff allowing certain changes to the DCRs (such as those needed to conform to the revised 10 CFR 50.59) within the existing DCR backfit provisions.

The Commission received similar comments from General Electric Company, Entergy, and Exelon in November 2001. The Commission disagrees with these comments and has concluded that it is necessary to amend § 52.63(a)(1) to allow changes to the design certification rules that reduce unnecessary regulatory burden, or do not constitute a backfit.

The current § 52.63(a)(1) (proposed § 52.127(a)(1)) was also modified to replace “a modification” with “the change,” in order to clarify that the three criteria for changes apply to modifications, rescissions or imposition of new requirements. Also, the Commission is clarifying the proposed § 52.127 to be consistent with its original intent (refer to 54 FR 15372; April 18, 1989) that the special backfit requirements apply to the certification information in the generic design control documents, not to the provisions in the design certification rules, e.g., Section VI.E of Appendix A to 10 CFR Part 52. Any proposed changes to these provisions that set forth how the design certification rules are to be used are controlled by the normal backfit requirements in 10 CFR 50.109.

The proposed rule would amend the current § 52.63(a)(2) (proposed § 52.127(a)(2)) to delete the reference to § 52.63(a)(4) (proposed § 52.127(a)(4)). The reference to § 52.63(a)(4) was in error because this paragraph discusses the finality of the findings required for issuance of a combined license or operating license, whereas § 52.63(a)(2) deals with modifications that the NRC may impose on a design certification rule under § 52.63(a)(3) or § 52.63(b)(1) (proposed § 52.127(a)(3) or § 52.127(b)(1)). No substantive change is intended by the amendment which merely clarifies the original intent of the rule.

#### (5) Standard Design Approvals

The proposed rule would amend the current Section 3 of Appendix O to 10 CFR Part 52 (proposed § 52.135) to clarify that applications for standard design approvals should contain all of the applicable technical information required by § 50.34. The amendment would also require applications for standard design approvals to provide the same technical information required for applications for standard design certifications (e.g., demonstration of compliance with any technically relevant Three Mile Island requirements, proposed technical resolutions of unresolved safety issues and medium- and high-priority generic safety issues, and a design-specific probabilistic risk assessment (PRA)). This clarification is consistent with past practice regarding applications for future designs and would implement the Commission's Policy Statements on Severe Reactor Accidents (50 FR 32138, August 8, 1985) and Nuclear Power Plant Standardization (52 FR 34884, September 15, 1987). This amendment would not require applicants to provide proposed ITAAC because standard design approvals are referenced in applications for construction permits and operating licenses under 10 CFR Part 50, and the verification process used for 10 CFR Part 50 applications does not use ITAAC.

The proposed rule would amend the current Appendix O to 10 CFR Part 52 (proposed § 52.139) to specify that the duration of a standard design approval is for 5 years. In a letter dated November 13, 2001 (comment 18.a), NEI commented:

Industry recommends FDAs be valid for 15 years. This is consistent with Commission direction in COMSECY-94-025 to update the lead plant FDA to provide a 15 year duration instead of the five years initially provided. The ABWR and System 80+ FDAs were so revised in 1994; the designs were certified in 1997.

The Commission disagrees with industry's recommendation and believes that NEI's discussion of the history of this issue is inaccurate. All of the FDAs for the three certified designs were originally issued for a five-year duration because there was no certainty that design certifications would be issued. Only after design certifications were issued for the ABWR and the System 80+ did the Commission direct, for consistency, that the FDAs be revised to provide the same term as for the design certification. This action did not change the Commission's policy for FDAs issued by themselves. Because this proposed rule would decouple the FDA from the design certification, the staff proposes to continue and codify the Commission's policy on duration of an FDA. The proposal for a 5-year duration for standard design approvals is consistent with past practice and with the Commission's Policy Statement on Standardization of Nuclear Power Plants (43 FR 38954, August 31, 1978).

#### (7) Combined Licenses

The proposed rule would amend the current § 52.73 (proposed § 52.203(a)) to clarify that a site report issued under Subpart B of Part 52 may also be referenced in an application for a combined license application filed under 10 CFR Part 52. This amendment would also add the requirements in the current § 52.63(c) (proposed § 52.127(c)) to the new § 52.203(b) to clarify that this requirement applies to applicants for a combined license. This provision requires that, prior to granting a combined license which references a standard design certification, information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if such information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certified design. No substantive change

is intended by the restatement of this requirement. In a letter dated April 3, 2001 (comments 3 and 3.a), NEI agreed with the proposed change but recommended that the last sentence of § 52.63(c) be deleted and the remaining provision be added to the current § 52.79 rather than the current § 52.73. The Commission agrees with NEI that 10 CFR Part 52 should be modified to clarify that the requirement in current § 52.63(c) applies to applicants for a combined license, and that the last sentence be deleted. However, the Commission is adding the remaining provision to what was § 52.73(b) (proposed § 52.203(b)) and not to § 52.79 (proposed § 52.211) as recommended by NEI.

The proposed rule would amend the current § 52.78 (proposed § 52.209) to clarify the requirements applicable to an applicant for, and holder of, a combined license with respect to training program required by 10 CFR 50.120. As currently written, § 52.78 simply indicates that the *application* must demonstrate compliance with the training program requirements in § 50.120. There is no explicit requirement with respect to the applicant/licensee to implement the training program. Furthermore, proposed § 52.215(b) indicates that, after a combined license is issued but before the Commission has authorized operation under § 52.231, the combined license holder shall comply with all requirements in Title 10 of the Code of Federal Regulations applicable to holders of construction permits for nuclear power reactors. However, § 50.120 refers to a “nuclear power plant applicant;” therefore, § 50.120 would not apply to a combined license holder even under the language of proposed § 52.215(b).

To remove any ambiguity in this matter, the Commission is proposing to revise in its entirety the language in current § 52.78, which is being re-designated as § 52.209. The proposed rule provides that the application must “describe” the training program required by § 50.120. In addition, the proposed rule states that the training program described in the application must be “established, implemented, and maintained” no later than eighteen (18) months prior to the scheduled date for initial loading of fuel, as provided for in § 52.231(a). By

“established [and] implemented”, the Commission intends to distinguish between the requirement to merely “describe” the training program in the application, versus the requirement for the combined license holder to establish (*e.g.*, establish a training organization, fill staff positions, write procedures, *etc.*) and implement (*i.e.*, perform training of applicable operating plant personnel in accordance with § 50.120) the training program. The proposed rule also clarifies that the eighteen (18) month period by which the training program must be established and implemented is measured from the combined licensee’s scheduled date for fuel load under proposed § 52.231(a) (current § 52.103(a)).

#### (8) Referencing an Early Site Permit

The proposed rule would amend current §§ 52.39 and 52.79 (proposed § 52.211) to require a license applicant referencing an early site permit to update and correct the emergency preparedness information provided under § 52.17(b). The issue of updating an early site permit was first raised by the Illinois Department of Nuclear Safety, who suggested in a September 28, 1994 letter that emergency plans and/or offsite certifications approved as part of an early site permit review be kept up-to-date throughout the duration of an early site permit and the construction phase of a combined license. In SECY-95-090, “Emergency Planning Under 10 CFR Part 52,” (April 11, 1995), the NRC staff stated that 10 CFR Part 52 does not clearly require an applicant referencing an early site permit to submit updated information on changes in emergency preparedness information and any emergency plans that were approved as part of the early site permit in accordance with § 52.18. SECY-95-090 indicated (p.4) that, in view of the lack of industry interest in pursuing an early site permit, resolution of this matter may be deferred until a “lessons learned” rulemaking updating 10 CFR Part 52 is conducted after the first design certification rulemakings are issued. Following public release of a draft SECY paper setting forth the NRC staff’s preliminary views on the licensing process for a combined license, the Nuclear Energy Institute (NEI) submitted a letter dated September 8, 1998 (comment 2.d),

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

The Commission agrees with the Illinois Department of Nuclear Safety that the emergency preparedness information approved when the early site permit was issued must be updated if there is new information which may materially affect the Commission's earlier determination on emergency preparedness, or if the new information is needed to correct inaccuracies in the emergency preparedness information approved in the early site permit. In the absence of such an updating requirement, the NRC would bear the responsibility of identifying whether there is new information on emergency preparedness that necessitates a re-examination of the Commission's earlier emergency preparedness determinations for the early site permit, and the early site permit holder or applicant referencing the early site permit would be under no obligation to correct inaccurate emergency preparedness information in the early site permit or approved emergency plan. However, the Commission also agrees with NEI that a "continuous" early site permit update requirement would impose burdens upon the early site permit holder without any commensurate benefit if the early site permit is not subsequently referenced. Accordingly, the Commission has decided that § 52.39 and current § 52.79 (proposed § 52.211) should contain an updating requirement to be imposed upon the applicant referencing an early site permit.

The proposed rule redesignates paragraph (b) of current § 52.39 as paragraph (c), and adds a new paragraph (b) requiring an applicant for a construction permit, duplicate design license, or combined license whose application references an early site permit to update and correct the emergency preparedness information provided under § 52.17(b), and to discuss whether the new information may materially change the bases for compliance with the applicable NRC requirements. A parallel requirement is included in proposed § 52.211(d)(1) to ensure that applicants for combined licenses referencing an early site permit will submit the updated emergency preparedness information. New information which materially changes the bases for compliance includes: (1) information which substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, as well as (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness in accordance with § 52.39(a)(1). New information which materially changes the Commission's determination of the matters in § 52.17(b), or results in modifications of existing terms and conditions under § 52.39(a)(1) would be subject to litigation during the construction permit, operating license or combined license proceedings in accordance with § 52.39(a)(2)(ii).

Not all new information on emergency preparedness would be subject to challenge in a hearing under § 52.39(a)(2)(ii). For example, an emergency plan may have to be updated to reflect current telephone numbers, the names of governmental officials whose positions and responsibilities are defined in the plan (e.g., the name of the current police chief for a municipality), or the current name of a hospital facility. Such corrections do not materially change the NRC's previously-stated bases for accepting the early site permit emergency plan; therefore, a hearing contention would not be admitted under § 52.39(a)(2)(ii) (or any other provision of § 52.39) in a proceeding for a license referencing the early site permit. By contrast,

if an emergency plan submitted as part of an early site permit relies upon a bridge to provide the primary path of evacuation, and that bridge no longer exists, the change could materially affect the NRC's previous determination that the emergency plan complied with the Commission's emergency preparedness regulations in effect at the time of the issuance of the early site permit. Thus, such information may be the basis for a change in the early site permit's terms and conditions related to emergency preparedness under § 52.39(a)(1), as well as the basis for a hearing contention under § 52.39(a)(2)(ii) - assuming that the requirements in 10 CFR Part 2 for admission of a contention are met.

An updating requirement for early site permit information other than emergency preparedness information does not appear to be necessary, inasmuch as it is unlikely that there would be changes to the information previously submitted on the site, such that a significant change to the site characteristics, terms, and conditions would be necessary if requested under the provisions of § 52.39(a)(2). If the site does not conform to the characteristics of the early site permit, an interested person may submit a petition under § 52.39(a)(2)(ii) alleging that the site does not conform to the early site permit. Accordingly, the proposed rule does not include an updating requirement for other early site permit information.

The proposed rule would amend § 52.79(a)(1) (proposed § 52.211(a)(1)), which currently requires a combined license application referencing an early site permit to contain information demonstrating that the design of the facility falls within the parameters specified in the early site permit, and information needed to resolve any other significant environmental issue not considered in the proceeding on the referenced early site permit. Currently, § 52.79(a)(1) requires a combined license application referencing an early site permit to contain information demonstrating that the design of the facility falls within the site parameters specified in the early site permit. However, § 52.79(a) does not explicitly require the application to address whether the terms and conditions specified in the early site permit under § 52.24 have

been met by the combined license holder, although this is implicit by the inclusion of any terms and conditions in the early site permit. To remove any ambiguity in this matter, the Commission is proposing to include a proposed § 52.211(a)(1)(iii) by requiring the application to address whether the terms and conditions specified in the early site permit under § 52.24 have been met (the Commission also proposes to rearrange paragraph (a)(1) by dividing the criteria to be met by an application referencing an early site permit into separate subdivisions (i), (ii) and (iii)). The Commission's intent, as reflected in the words, "have been met," is that all terms and conditions will be met prior to issuance of the combined license.

#### (9) Testing Requirements for Advanced Reactors

The proposed rule would amend the current § 52.79(b) (proposed § 52.211(b)) to revise the requirements for combined license applications that do not reference a design certification rule by adding the current § 52.47(b)(2) (proposed § 52.107(b)(2)) to the list of requirements in the proposed § 52.211(b)(1) that a combined license applicant must comply with. This amendment will provide consistency between the current advanced reactor testing requirements in Subpart B of Part 52 (§ 52.47(b)(2)) and the proposed testing requirements in Subpart C of Part 52 (§ 52.211(b)). This amendment will require a combined license applicant that references a custom advanced reactor design to also perform the design qualification testing required by the current § 52.47(b)(2) for design certification applicants. If a combined license application references a certified advanced reactor design, the qualification testing required by § 52.47(b)(2) will have been performed. The amendment also requires (proposed § 52.211(b)(3)) that if a licensed prototype plant (see definition in proposed § 52.3) is used to meet the qualification testing requirements in the current § 52.47(b)(2), additional requirements on siting, safety features, or operational conditions may be required for licensing, in order to

compensate for uncertainties associated with the performance of new or innovative safety features in the prototype plant.

The codification of testing requirements in the current § 52.47(b)(2) was a principal issue in the development of 10 CFR Part 52 (see Section II of 54 FR 15372; April 18, 1989). The testing requirements in § 52.47(b)(2), to demonstrate the performance of safety features for nuclear power plants that differ significantly from evolutionary light-water reactors or utilize simplified, inherent, passive, or other innovative means to accomplish their safety functions (advanced reactors), were included in 10 CFR Part 52 to ensure that these safety features will perform as predicted in the applicant's safety analysis report, that the effects of systems interactions are acceptable, and to provide sufficient data to validate analytical codes. The design qualification testing requirements may be met with either separate effects or integral system tests; prototype tests; or a combination of tests, analyses, and operating experience. These requirements implement the Commission's policy on proof-of-performance testing for all advanced reactors (see 51 FR 24643; July 8, 1986) and the Commission's goal of resolving all design issues before authorizing construction.

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

Exelon Generation and NEI commented on the addition of testing requirements for combined license applications, in letters dated November 13, 2001. NEI stated:

COL application requirements in Section 52.79(b)(1) have been modified to include a reference to the design certification application requirements of 52.47(b)(2)(i). Under this proposal, an applicant seeking a COL for a non-certified design that differs significantly from typical light water reactors would have to demonstrate safety feature performance through either (A) analysis, testing, or experience, or (B) full-scale prototype testing. This requirement is entirely appropriate for design certification applicants. However, as discussed below, we believe it is unnecessary to apply these requirements to COL applicants, and that the potential requirement for full-scale prototype testing is particularly inappropriate.

First, Part 52 should not be modified to open the door to requiring a COL applicant, who does not reference a certified design, to build and complete testing of a full-scale prototype before the granting of the license. The potential to require prototype testing to support issuance of a COL is contrary to Commission guidance in the Part 52 Statements of Consideration. The Commission clearly recognized “licensing the prototype for commercial operation” as a path open to applicants under Subpart C of Part 52 that could lessen the burden of having to demonstrate innovative designs through full scale prototype testing. We agree with the further statement by the Commission that, “[i]t is well to remember also that, under the rule, prototype testing is required only for certification or an unconditional design approval, if at all.” . . . In sum, through its existing requirements and regulatory authority, the NRC is assured of (1) adequate information to support required COL reviews and safety determinations, and (2) satisfactory demonstration of innovative design features

during startup and power ascension testing. The proposed new COL application requirements are unnecessary and should not be carried forward into the Part 52 NOPR [Notice of Proposed Rulemaking].

The Commission disagrees with NEI and Exelon regarding the need to perform qualification testing for new or innovative safety features in all advanced reactor designs. The Commission reformed the licensing process for new nuclear plants with the issuance of 10 CFR Part 52 in 1989 and required applicants to demonstrate that safety features will perform as predicted in their final safety analysis report. Although the focus of the NRC staff in 1989 was on applications for design certification, the Commission intended that testing to qualify 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 Commission to require testing for design certification (paper designs) and not require testing for applications to build and operate an advanced nuclear reactor.

Although the Commission has stated that it favors the use of prototypical demonstration facilities and that prototype testing is likely to be required for certification of advanced non-light-water designs (see policy at 51 FR 24646; July 8, 1986 and Section II of 54 FR 15372 on 10 CFR Part 52; April 18, 1989), the proposed rule does not mandate the use of a prototype plant. Rather, the proposed rule provides that if a prototype plant is used to qualify an advanced reactor design, then additional requirements may be required for licensing of the prototype to compensate for any uncertainties with the unproven safety features. Also, the prototype plant could be used for commercial operation. Therefore, the Commission proposes to amend § 52.79(b) (proposed § 52.211(b)) to implement its original intent in adopting 10 CFR Part 52 and its policy on advanced reactors that it is necessary to demonstrate the performance of new or innovative safety features through design qualification testing for all advanced reactors.

#### (10) Probabilistic Risk Assessments

The proposed rule would also amend the current § 52.79(b) (proposed § 52.211(b)) to adopt a requirement to submit a plant-specific PRA as part of an application for a combined license. The current § 52.79(b) references § 52.47(a)(1)(v), which requires a design-specific PRA within a design certification application. This amendment (§ 52.211(b)(2)) would require an application for a combined license to contain a plant-specific PRA that covers all of the nuclear plant design, including site-specific design features (e.g., the ultimate heat sink). If the combined license application referenced a certified design, this amendment (§ 52.211(b)(5)) would require the design-specific PRA to be updated to include site-specific design features and to account for any design changes. In a letter dated April 3, 2001 (comment 11.1a), NEI stated “we agree on the NRC vision for a plant-specific PRA at COL that supplements the DC PRA with any changes that affect the DC PRA plus site-specific (interface) design information.”

The purpose of the requirement for a plant-specific PRA is to identify and address potential design and operational vulnerabilities, gain insights about the risk of the design, assess the balance between preventive and mitigative features in the design, to determine quantitatively whether the design represents a reduction in risk over current operating plants, and to determine how the risk associated with the new design relates to the Commission’s safety goals. Accordingly, the Commission proposes to amend § 52.211(b) to require an application for a combined license to contain a plant-specific PRA.

#### (11) Resolution of ITAAC

The proposed rule would amend the current § 52.79(c) (proposed § 52.211(c)), current § 52.97(a) (proposed § 52.227(a)), current § 52.99 (proposed § 52.229(e)), and current §§ 52.103(a) and (g) (proposed §§ 52.231(a) and (g)) to provide an applicant for a combined license with a process for resolving certain acceptance criteria in one or more of the ITAAC required by the proposed § 52.211(c) before issuance of the combined license. In a letter

dated November 13, 2001 (comment 20), NEI recommended that Subpart C be revised to allow for completion of design acceptance criteria (DAC) at the COL application stage. NEI made this recommendation because applicants might want to complete certain DAC before construction. DAC are special design certification rule ITAAC. DAC set forth processes and criteria for completing certain design information, such as information about the digital instrumentation and control system. DAC were originally written to be verified as part of the normal, post-combined license, ITAAC verification process.

The Commission agrees with NEI's recommendation that combined license applicants be permitted to demonstrate DAC completion as part of the combined license application, for several reasons. First, completion of the design matters covered by DAC before the issuance of a combined license is consistent with the Commission's original concept for design certification and issuance of a combined license. When it adopted 10 CFR Part 52, the Commission intended that a design certification contain final and complete design information. Allowing a finding of acceptable completion of DAC before issuance of a combined license is, therefore, consistent with the Commission's original intent. Second, completion of DAC before issuance of the combined license is consistent with the Commission's goal of resolving issues before construction. Determining whether DAC have been successfully completed before issuance of the combined license avoids the possibility that improperly completed DAC will result in the construction of improperly designed structures, systems, and components. Finally, the Commission believes that completion of DAC before issuance of the combined license will enhance public confidence in the overall licensing process because the public will have an opportunity to challenge whether the design has been properly completed before construction begins. Accordingly, the Commission proposes that a finding of successful completion of DAC may be made when a combined license is issued, if the combined license applicant demonstrates that the DAC have been successfully completed. This new process would also

allow findings on successful completion of inspections or tests of components procured before the issuance of the combined license.

The proposed rule would also amend the current § 52.99 (proposed § 52.229 (b), (c) and (d)) and the current § 52.103 (proposed § 52.231(h)) to incorporate rule language from the design certification rules in 10 CFR Part 52 regarding the completion of ITAAC (see paragraphs IX.A and IX.B.3 of Appendix A to Part 52). During the preparation of the design certification rules for the ABWR and System 80+ designs, the NRC staff and nuclear industry representatives agreed on certain requirements for the performance and completion of the inspections, tests, or analyses in ITAAC. In the design certification rulemakings, the Commission codified these ITAAC requirements into Section IX of the rules. The purpose of the requirement in paragraph (b) of proposed § 52.229 is to make it clear that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been successfully completed. Paragraph (c) of proposed § 52.229 requires the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met. Paragraph (d) simply states the options that a licensee will have in the event that it is determined that any of the acceptance criteria in the ITAAC have not been met. Finally, paragraph (h) of § 52.231 states that ITAAC do not, by virtue of their inclusion in the DCD, constitute regulatory requirements after the licensee has received authorization to load fuel or for renewal of the license. However, subsequent modifications must comply with the design descriptions in the design control document unless the applicable requirements in the current § 52.97 and Section VIII of the design certification rules have been complied with.

In a letter dated April 3, 2001 (comment 23), NEI stated “consider incorporating DCR general provisions into Subpart C as appropriate.” The Commission has decided to add these ITAAC requirements to proposed § 52.229 because it believes that these provisions embody general principles that are applicable to all holders of combined licenses.

(12) Commission Finding on Acceptance Criteria

The proposed rule would amend the current § 52.83 (proposed § 52.215) and the current § 52.99 (proposed § 52.229(e)) to clearly state the Commission’s determination that the NRC staff should be responsible for ensuring (through its inspection and audit activities) that the combined license holder performs and documents the completion of inspections, tests and analyses in the ITAAC. Currently, § 52.99 states that “the Commission shall ensure that the required inspections, tests, and analyses are performed and, prior to operation of the facility, shall find that the prescribed acceptance criteria are met.” When Part 52 was first adopted by the Commission in 1989 (54 FR 15372, April 18, 1989), § 52.99 provided that the NRC staff shall ensure that the inspections, tests and analyses in the ITAAC are performed, and did not refer to the Commission finding on acceptance criteria being met. The requirement for a Commission finding on acceptance criteria was contained in § 52.103(g). The Commission adopted the current language of § 52.99 in 1992 (57 FR 60975, December 23, 1992) to reflect changes to Section 185 of the AEA made by Congress in the Energy Policy Act of 1992 (1992 EPA), which states:

Following issuance of the combined license, the Commission shall ensure that the prescribed inspections, tests, and analyses are performed and, prior to operation of the facility, shall find that the prescribed acceptance criteria are met.

Thus, the revisions to § 52.99 adopted by the Commission in 1992 simply reflect the language of the 1992 EPA. However, the Commission does not believe that Congress, by adopting language in Section 185 stating that the Commission shall ensure that the ITAAC are

performed, intended to alter the Commission's determination that the NRC staff is responsible for ensuring that "the required inspections, tests and analyses in the ITAAC are performed," and by doing so alter the Commission's long-standing delegation of inspection and oversight activities to the NRC staff. For these reasons, the Commission proposes that § 52.99 (proposed § 52.229(e)) state that the NRC staff shall be responsible for ensuring that inspections, tests or analyses in the ITAAC have been performed. The requirement for a Commission finding on acceptance criteria will continue to be addressed separately in § 52.103(g) (proposed § 52.231(g)).

In a letter dated February 22, 1993, the Nuclear Management and Resources Council, Inc. (NUMARC) stated:

There is nothing in Title XXVIII or its legislative history which compels a change in the Staff responsibilities from that reflected in prior Section 52.99. Indeed, any other implementation of Section 52.99 would be wholly unworkable. Accordingly, it is our understanding that the reference to "the Commission" in amended Section 52.99 is to be read as authorizing the Commission to delegate to the Staff the responsibility for overseeing ITAAC performance during the period of facility construction; and further that this is the Commission's intention.

Responsibility for the pre-operational finding of acceptance criteria conformance would, of course, be the responsibility of the Commission, as reflected in both amended Sections 52.99 and 52.103(g).

The proposed rule is consistent with NUMARC's recommendation.

The requirements in the proposed § 52.229(e) will be limited to the responsibilities of the NRC staff. The staff will ensure that the inspections, tests, or analyses in the ITAAC have been performed and will publish notices in the Federal Register of the licensee's claim that certain inspections, tests, or analyses have been completed and the acceptance criteria have been

met. The NRC staff will perform periodic inspections during construction of the facility and implementation of the licensee's operational programs, e.g., emergency planning and training. The NRC staff will issue reports on these inspections, which will include interim conclusions on the ITAAC verification program, and will make these reports publically available. At the conclusion of construction, the staff will make a recommendation to the Commission on its assessment of the licensee's completion of ITAAC. If the Commission determines that all of the acceptance criteria in the ITAAC for the combined license have been met, it will make the finding required under proposed § 52.231(g).

Consistent with the language in proposed § 52.229(e), the proposed rule would also amend the current § 52.83 (proposed § 52.215(c)) to state that the requirements in 10 CFR Part 50 that are applicable to holders of operating licenses become applicable to holders of combined licenses after the Commission's finding of successful ITAAC completion under current § 52.103(g) (proposed § 52.231(g)), rather than referring to the Commission finding under the current § 52.99. As discussed above, the Commission's 1992 rulemaking amended § 52.99 to refer to the Commission's finding of ITAAC completion, and amended § 52.83 to refer to the Commission's finding under § 52.99. Inasmuch as the Commission finding and authorization of operation would be addressed in proposed § 52.231(g), it follows that proposed § 52.215(c) should refer to the Commission's authorization of operation under § 52.231(g) rather than the NRC staff's activities under proposed § 52.229.

#### (13) Duration of a Combined License

The proposed rule would amend the current § 52.83 (proposed § 52.215) and the current § 52.97 (proposed § 52.227(e)) to correct an error in the beginning date for the term of a combined license. Currently, § 52.83 states that "the initial duration of the [combined] license may not exceed 40 years from the date on which the Commission makes the findings required under § 52.99." Because it takes time to construct a nuclear plant, the actual term of a

combined license under § 52.83 would be longer than 40 years. The AEA, as currently written, does not give the Commission authority to issue a combined license expiring 40 years from the date that the Commission makes a finding that all ITAAC have been met. Instead, Section 103.c. of the AEA states that a license issued under that section shall be “issued for a specified period, as determined by the Commission . . . *but not exceeding forty years*” (emphasis added). Because a combined license is a single license,<sup>1</sup> its term cannot exceed 40 years from the date of its issuance. Nothing in the Energy Policy Act of 1992 (1992 EPA), Pub. L. 102-486, which sets forth the requirements for issuing combined licenses, suggests that the 40-year limit in Section 103.c. does not apply to combined licenses issued under Section 189.a.(1)(B). The legislative history of the 1992 EPA does not disclose any congressional consideration of the issue. Accordingly, the Commission concludes that Section 103.c. of the AEA limits the term of a combined license to 40 years from the date of issuance of the combined license, and a correction to the language in the current § 52.83 is necessary. The Commission proposes to

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<sup>1</sup>When 10 CFR Part 52 was originally promulgated, the Commission cited Section 161(i) of the AEA as authority to issue regulations governing combined licenses. That section authorizes the Commission to, inter alia, “combine in a *single* license one or more of such activities” [for which a license is required by the AEA] (emphasis added). This AEA provision was apparently included in response to testimony submitted to the Joint Committee on Atomic Energy complaining about the “multiplicity of licenses” required under the proposed legislation and seeking revisions that would authorize the Commission to issue a “*single license* to cover all integrated operations” (emphasis added). See Hearings Before the Joint Committee on Atomic Energy (“Hearings”), 83<sup>rd</sup> Congress, 2d Sess. 79 (1954) (testimony of Walker L. Cisler, President, Detroit Edison Co.); see also Hearings at 112-113 (testimony of Paul W. McQuillen, Chairman of the joint legal committee for Dow Chemical-Detroit Edison-Power Reactor Development Corporation), 352 (testimony of F.K. McClune, General Manager, Atomic Products Division, General Electric Company), 64 (testimony of E. Blyth Stason, Dean, Michigan Law School). The 1992 EPA modified Section 189 of the AEA to add specific requirements for the issuance of combined licenses and prerequisites for operation under a combined license, but did not alter either Section 161.i. or Section 103.c. The Senate Report on S.1220 (the only report to discuss the nuclear licensing provisions) stated: “The new subsection b. [of Section 189] reaffirms the NRC’s existing authority and sets out specific requirements governing the issuance of a combined license (S. Rep. No. 102-72, 102<sup>nd</sup> Cong. 2d Sess. at 292). Thus, it appears that Congress intended to reconfirm the NRC’s authority under the preexisting provisions of the AEA to issue combined licenses, and did not intend to change the 40-year limit in Section 103.c. on the term of a license.

limit the term of a combined license to forty years from the date of issuance of the combined license in proposed §§ 52.215 and 52.227(e).<sup>2</sup>

#### (14) Combined License Change Process

The proposed rule would amend the current § 52.97 (proposed § 52.227) to clarify the applicability of the change processes in 10 CFR Part 50 and Section VIII of the design certification rules in 10 CFR Part 52 to a combined license. This amendment will add § 52.227(c), which states that the change processes in 10 CFR Part 50 apply to a combined license that does not reference a design certification rule. This amendment will also add § 52.227(d), which states that the change processes in Section VIII of the design certification rules apply to changes within the scope of the referenced certified design. However, if the proposed change affects the design information that is outside of the scope of the design certification rule, the Part 50 change processes apply unless the change also affects the design certification information. For that situation, both change processes may apply.

In a letter dated November 13, 2001 (comment 21(a)(2)), NEI recommended that proposed §§ 52.227(c) and (d)(2) state that changes outside the scope of a certified design are subject to “the applicable change control requirements in 10 CFR Part 50, e.g., 10 CFR 50.59, 50.54 or 50.90.” The Commission has decided to propose this amendment to clarify which change processes are applicable to a combined license and this amendment is consistent with NEI’s recommendation.

#### (15) Design Certifications for ABWR, System 80+, and AP600

The proposed rule would amend paragraphs VI.B.4, 5, and 6 of the three design certification rules in 10 CFR Part 52, Appendices A, B, and C (for U.S. ABWR, System 80+,

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<sup>2</sup>The Commission has proposed legislation that would authorize the 40-year term to begin with the authorization to operate. Should such legislation be enacted, these provisions in the regulations will be modified.

and AP600 designs, respectively), by substituting the phrase “but only for that *plant*” for the erroneous phrase “but only for that *proceeding*” (emphasis added). The new phrase correctly characterizes the scope of issue resolution in three situations. Paragraph VI.B.4 describes how issues associated with a design certification rule are resolved when an exemption has been granted for a plant referencing the design certification rule. Paragraph VI.B.5 describes how issues are resolved when a plant referencing the design certification rule obtains a license amendment for a departure from Tier 2 information. Paragraph VI.B.6 describes how issues are resolved when the applicant or licensee departs from the Tier 2 information on the basis of paragraph VIII.B.5, which waives the requirement to get NRC approval. Thus, once a matter (e.g., an exemption in the case of paragraph VI.B.4) was addressed for a specific plant referencing a design certification rule, the adequacy of that matter *for that plant* would not ordinarily be subject to challenge in any subsequent proceeding or action (such as an enforcement action) listed in the introductory portion of paragraph IV.B, but there would not be any issue resolution on that subject matter for *any other plant*. Unfortunately, the three design certification rules use the phrase “but only for that proceeding,” which may lead to the erroneous conclusion that issue resolution exists only in the proceeding in which the matter was approved and/or adjudicated, and not in all subsequent proceedings for that plant.

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

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

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

In a letter dated November 13, 2001, NEI stated that the staff should use the “substantial increase” threshold for determining when prior NRC approval is required for changes affecting severe accident information.

Part 52 design certifications contain both traditional design basis and beyond-design basis (severe accident) information. When establishing the “50.59-like process” for the design certification rules (DCRs), the Commission recognized

that greater flexibility should be afforded licensees (vis-à-vis design basis information) for making changes that affect severe accident-related information.<sup>3</sup> In the DCRs, the normal “any increase” threshold then in effect was adopted for determining when prior NRC approval was required for changes affecting design basis information. To account for the increased uncertainty in severe accident issue resolution, the Commission established the “substantial increase” threshold for severe accident-related information.

To conform the DCRs to the recently revised 10 CFR 50.59, the draft rule correctly replaces the old “any increase” threshold with the new “minimal increase” threshold for design basis information. However, the draft rule incorrectly applies the “minimal increase” threshold for severe accident-related information as well. Doing this would eliminate the higher “substantial increase” threshold intended by the Commission for severe accident-related information. Moreover, the “minimal increase” threshold, defined in regulatory guidance as less than 10% increase in the baseline core damage frequency,<sup>4</sup> would be unduly restrictive for licensees given the very low likelihood (e.g., 10E-8) of beyond design basis events.

The Commission disagrees with NEI’s recommendation. At the time that the “substantial increase” threshold for severe accident information was created for the § 50.59-like process, the consideration of revisions to § 50.59 had not begun. Industry expressed concern with using the “any increase” threshold for severe accident information because of increased uncertainty in severe accident issue resolution. After consideration, the “substantial increase” threshold was adopted for the § 50.59-like process to resolve industry’s concern with the “any increase” threshold in the former § 50.59 change process, but the “substantial increase” threshold was never defined. Thereafter, the Commission engaged in extensive consideration of the threshold for changes as part of the § 50.59 rulemaking, and the resolution of this issue is reflected in the final § 50.59 rule. As part of that resolution, the Commission defined, with stakeholder input, the term “more than a minimal increase.” Therefore, the Commission is proposing the “more than a minimal increase” threshold for the severe accident information, which uses a threshold for change that will have uniform implementation, and which uses a

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<sup>3</sup> See the Statements of Consideration for the System 80+ DCR (62 FR 27867, May 21, 1997)

<sup>4</sup> NEI 96-07, Revision 1 (endorsed by Regulatory Guide 1.187)

term that has been defined in guidance developed for the new § 50.59 change process with broad stakeholder input.

*B. 10 CFR Part 2, Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders*

The proposed rule would amend §§ 2.110, 2.400, 2.401, 2.402, 2.403, 2.404, 2.406, 2.500, 2.501, and 2.502 to correct references to former 10 CFR Part 52 appendices that have been redesignated as subparts.

*C. 10 CFR Part 20, Standards for Protection Against Radiation*

The proposed rule would amend § 20.1002 to clarify that the regulations in 10 CFR Part 20 also apply to licenses issued under 10 CFR Part 52. This conforming change was inadvertently overlooked when the Commission originally promulgated 10 CFR Part 52.

*D. 10 CFR Part 21, Reporting of Defects and Noncompliance*

The proposed rule would amend §§ 21.2, 21.3, and 21.21 to clarify the applicability of 10 CFR Part 21 to individuals, corporations, partnerships, or other entities doing business within the United States, and directors and responsible officers of such organizations, that hold a permit or license under 10 CFR Part 52. These conforming changes would correct an oversight when the Commission first adopted 10 CFR Part 52, to ensure that the requirements in 10 CFR Part 21 apply to applicants for, and holders of licenses under 10 CFR Part 52, as well as to suppliers of basic components to such licensees.

*Combined licenses, manufacturing licenses, duplicate design licenses.*

The proposed rule would make 10 CFR Part 21 applicable to applicants for, and holders of combined licenses, manufacturing licenses, and duplicate design licenses under 10 CFR Part 52, and suppliers of basic components to such applicants and holders, by amending paragraphs (a), (b), and (c) of § 21.2 regarding the scope of 10 CFR Part 21 and amending the definitions of *basic component*, *commercial grade item*, *critical characteristics*, *dedicating entity*,

*dedication, defect, and substantial safety hazard* in § 21.3. In addition, the proposed rule would amend § 21.21 to clearly state when a director or responsible officer subject to 10 CFR Part 21 must notify the Commission that the director or officer has information reasonably indicating a failure to comply or a defect affecting the construction or operation of a facility or an activity that is subject to the licensing requirements under 10 CFR Part 52 or affecting a basic component supplied for a facility or an activity that is subject to the licensing requirements under 10 CFR Part 52. The Commission notes that a supplier of safety-related analyses and services to a licensee under Part 52 is subject to Part 21, inasmuch as such services constitute “basic components;” this is no different than the applicability of Part 21 to a supplier of such analyses and services to a licensee under Part 50.

*Early site permits.*

With respect to early site permits, the Commission proposes to use a different approach, such that the requirements of Part 21 do not apply to applicants for early site permits, or holders of early site permits so long as the early site permit is not referenced in any license application. During the pendency of the early site permit application before the NRC, the applicant would be required by 10 CFR 50.9, “Completeness and accuracy of information,” to notify the Commission of any information having a “significant implication for public health and safety or the common defense and security” with respect to the matters covered in the application, pursuant to proposed § 52.111. Failure to abide by the completeness and accuracy requirements in § 50.9 would subject the applicant to potential criminal liability under § 52.113 (proposed § 52.403). In addition, under current § 52.9, the early site permit applicant would be subject to penalties for deliberate misconduct, including submission to the NRC of information known to be incomplete or inaccurate in some material aspect. Finally, during the pendency of an early site permit application, the application has no operative effect with respect to issue resolution under § 52.39; consequently, an early site permit application itself could not result in a “substantial

safety hazard” by virtue of the application being referenced in a nuclear power plant licensing proceeding. Therefore, the Commission does not believe that adopting the regulatory overlay of Part 21 during the pendency of an early site permit application, is necessary to effectuate the Commission’s regulatory responsibilities under the AEA, as amended, including providing reasonable assurance of adequate protection to public health and safety or common defense and security.

The Commission does not believe that Part 21 should apply to the early site permit holder after the early site permit has been issued, but before the holder has referenced the permit in a license application<sup>5</sup>. With one exception, the early site permit does not authorize any action by the holder with respect to the construction or operation of a nuclear power plant. The exception is when the early site permit authorizes the holder to conduct the site preparation activities permitted under 10 CFR 50.10(e)(1) (commonly referred to as limited work authorization-1, or LWA-1, activities). However, these activities are related to site clearing and preparation, and do not permit any construction (including subsurface preparation) for “structures, systems and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.” Thus, the conduct of LWA-1 activities do not appear to have any reasonable possibility of resulting in a “substantial safety hazard.” Furthermore, the inherent nature of an early site permit is site-specific and not susceptible to generic or wide-ranging applicability. For these reasons, the Commission

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<sup>5</sup>The Commission 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. Since the early site permit is a license, the relevant requirements of Part 21 are those applicable to a licensee.

proposes that Part 21 should not apply to an early site permit holder until the permit is referenced by a license applicant.

Once an early site permit holder references the permit in a license application, the Commission believes that the holder should be subject to Part 21. The Commission's safety review of a license application referencing an early site permit is limited in accordance with §§ 52.39 and 52.79 (proposed § 52.211), under the precept that the site parameters, terms, and conditions which define the envelope for safe siting of a nuclear power plant have been determined by the NRC in the early site permit proceeding. If the early site permit holder discovers a significant safety concern with respect to its site (e.g., that the specified site parameter for seismic acceleration is less than the projected acceleration due to new information), the concern should be reported to the NRC so that it may be considered in the review of the application referencing the early site permit. This reporting attains special importance given the Commission's proposal (see discussion in Section III.A.8 on referencing an early site permit) not to impose an updating requirement for early site permit information other than that related to emergency preparedness. Accordingly, the Commission concludes that the early site permit holder should be subject to Part 21 once it references the permit in a license application.

The Commission believes that changes to Part 21 are unnecessary to reflect these determinations with respect to early site permit applicants and holders. A licensee's reporting requirements in Part 21 apply only with respect to "basic components" used or to be used in an NRC-licensed or otherwise regulated facility. The safety-related analyses and consulting services supplied to an applicant for an early site permit appears to fall within the definition of "basic component," in that they constitute "safety-related design [and] analyses . . . associated with component hardware" (See 10 CFR § 21.3, "Basic component," paragraph (3)). Thus, Part 21 could be interpreted as applying to the early site permit holder immediately upon the

permit's issuance. However, there appears to be little reasonable likelihood of a "substantial safety hazard" unless and until the early site permit has been referenced by the permit holder in a license application. Once the early site permit has been referenced, the potential for a substantial safety hazard clearly exists if a known defect in site parameters, terms, or conditions defining the envelope for safe plant operation is not disclosed, and a plant is designed, constructed, and allowed to operate which does not reflect the actual limiting parameters and conditions of the site. Accordingly, the Commission concludes that it is reasonable and appropriate to limit the applicability of Part 21 to the early site permit holder after the holder references the early site permit in a license application.

The Commission also proposes that Part 21 apply to suppliers of safety-related analyses and services to an early site permit holder in the same manner and extent as Part 21 applies to the early site permit holder. Such suppliers would be subject to Part 21 only after the early site permit holder references the permit in a license application.

*Design certification rules.*

Similar to the approach for early site permit applicants and holders, the Commission proposes that the requirements in Part 21 should not apply to the applicant/vendor for a design certification (and/or its successors) during the pendency of its design certification application. During the pendency of the design certification application, the applicant/vendor would be required by 10 CFR 50.9, "Completeness and accuracy of information," to notify the Commission of any information having a "significant implication for public health and safety or the common defense and security" with respect to the matters covered in the application, pursuant to proposed § 52.111. Failure to abide by the completeness and accuracy requirements in § 50.9 would subject the applicant/vendor to potential criminal liability under § 52.113 (proposed § 52.403). In addition, under current § 52.9, the applicant for a design certification is subject to penalties for deliberate misconduct, including submission to the NRC of information known to be

incomplete or inaccurate in some material aspect. Finally, during the pendency of a design certification application, the application has no operative effect with respect to issue resolution under current § 52.63 (proposed § 52.127); consequently, a design certification application itself could not result in a “substantial safety hazard” by virtue of the application being referenced in a nuclear power plant licensing proceeding. Therefore, the Commission does not believe that adopting the regulatory overlay of Part 21 during the pendency of a design certification application is necessary to effectuate the Commission’s regulatory responsibilities under the AEA, as amended, including providing reasonable assurance of adequate protection to public health and safety or common defense and security.

The Commission also believes that the reporting requirements in Part 21 should not apply to the design certification applicant/vendor *after* the Commission issuance of a final design certification rule but *before* the design certification rule is referenced by at least one applicant/licensee (nor should either §§ 52.9 or 52.111 be modified to make them applicable to the design certification applicant/vendor). The Commission does not believe that a design certification rule would reasonably result in a “substantial safety hazard” so long as the design certification rule is not actually referenced in a license application (and thereafter incorporated by reference into a license). It is true that, unlike an early site permit, a design certification rule is of general applicability and that a complete nuclear power plant design could be provided by an entity other than the original design certification applicant/vendor (see § 52.73 (proposed § 52.203)). Nonetheless, unless the other entity provides a design which is subsequently referenced in an NRC license application, there is no “substantial safety hazard” created (although the Commission acknowledges that the entity may incur significant redesign costs if the entity completes substantial parts of the design before submission of the application, only to find upon submission of the application that there were significant defects in the certified design). Upon weighing of all relevant factors, the Commission proposes that Part 21 should not

apply to the design certification applicant/vendor until a final, Commission-approved design certification rule is referenced by at least one applicant/licensee.

However, the Commission believes that once a design certification rule is referenced by an applicant, the design certification applicant/vendor should be subject to Part 21. The Commission's safety review of a license application referencing a design certification rule is limited in accordance with § 52.63 (proposed § 52.127) and § 52.79 (proposed § 52.211). If the design certification applicant/vendor has discovered a significant safety concern with respect to its certified design, it should be reported to the NRC so that it may be considered in the review of the application referencing the design certification rule. While this places a continuing obligation on the design certification applicant/vendor to monitor whether its design has been referenced in a license application, as a practical matter it is likely that the license applicant will have contractually engaged the design certification applicant/vendor prior to submitting the application. In any event, the Commission concludes that the design certification applicant/vendor should be subject to Part 21 after its design certification has been referenced by an applicant for a license.

The Commission believes that, with one exception, changes to Part 21 are unnecessary to reflect these determinations with respect to design certification applicants/vendors. Designs submitted for certification are "basic components," as defined in § 21.3, as are any supporting analyses inasmuch as they constitute "safety-related design [and] analysis . . . associated with component hardware whether these services are performed by the component supplier or not." If the design certification applicant/vendor provides the certified design to a license applicant pursuant to contract or agreement, the design certification applicant/vendor "supplies" the basic component, see § 21.3. However, there is a possibility that an entity other than the applicant/vendor of a design which was certified in a design certification rule may supply the complete plant design to a referencing license applicant. See § 52.73 (proposed § 52.203). For

these reasons, the Commission is considering a change to the definition of “supplying or supplies” in § 21.3 to ensure that a design certification applicant/vendor who does not pursuant to contract supply to a license applicant the complete design for the design certification, is also subject to Part 21 for this special situation.

For the reasons discussed earlier, the Commission believes that it is reasonable and appropriate to limit the applicability of Part 21 such that it is applicable once the design certification rule has been referenced by an applicant, permit holder, or licensee. Therefore, although the potential ambit of Part 21 extends to an applicant/vendor of a design certification after issuance of a design certification rule, the Commission has decided not to extend the applicability of Part 21 in such a fashion. By contrast, once the design certification rule has been referenced, the potential for a substantial safety hazard exists if a known defect in a design certification rule is not disclosed, the remainder of the plant is designed, the plant constructed, and subsequently allowed to operate. Accordingly, the Commission concludes that Part 21 should apply to the design certification applicant/vendor after the design certification rule has been referenced by a license applicant. Finally, the Commission concludes that Part 21 should apply to suppliers of safety-related analyses and services to a design certification applicant/vendor in the same manner and extent as Part 21 applies to the design certification applicant.

*E. 10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities*

The proposed rule would amend paragraph (a)(1) of § 50.109 (backfit rule) to clearly state the applicability of the backfit rule to some of the licensing processes 10 CFR Part 52 and the date that backfit protection commences for those licensing processes. The licensing processes to which the backfitting provisions in § 50.109 apply are standard design approvals, combined licenses, manufacturing licenses, and duplication design licenses issued under subparts E, G, H, and I of 10 CFR Part 52, respectively. The backfitting requirement in

§ 50.109 does not apply to early site permits, early site reviews, and standard design certifications issued under subparts A, B, and D, respectively, in as much as these licensing processes have their own special backfitting provisions (the special backfit requirements set forth in § 52.39, current sections 5 and 6 of Appendix Q (proposed § 52.47), and current § 52.63(a) (proposed § 52.127(a)) apply to early site permits, early site reviews, and standard design certifications, respectively). Paragraph vii of § 50.109(a)(1) sets forth the applicability of these special backfitting provisions for a combined license that references an early site permit, early site review, or design certification rule.

The proposed rule would also remove Appendices M, N, O, and Q from 10 CFR Part 50. These appendices were transferred to 10 CFR Part 52 when it was first promulgated (54 FR 15372, April 18, 1989). However, the Commission failed to remove those appendices from 10 CFR Part 50, though the Commission intended to do so (see 54 FR 15385, April 18, 1989).

*F. 10 CFR Part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions*

The proposed rule would amend paragraph (b)(6) of § 51.20, "Criteria for and identification of licensing and regulatory actions requiring environmental impact statements," to make clear that issuance of a manufacturing license requires preparation of an environmental impact statement or a supplement to an environmental impact statement. Paragraph (b), which defines types of actions that require an environmental impact statement or a supplement to an environmental impact statement would replace the current reference to Appendix M with a reference to Subpart H of 10 CFR Part 52 which is the proposed subpart that sets forth the process for manufacturing licenses, formerly contained in Appendix M.

*G. 10 CFR Part 72, Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste*

The proposed rule would amend § 72.210 to indicate that a general license would be issued for the storage of spent fuel in an independent spent fuel storage installation at power reactor sites to persons authorized to possess or operate nuclear power reactors under a combined license or duplicate design license under 10 CFR Part 52. The proposed rule would also amend the requirements in § 72.218(b) regarding an application for termination of a reactor operating license and the removal of the spent fuel stored at the reactor site to indicate that this provision also applies to applications for termination of a combined license or duplicate design license.

#### *H. 10 CFR Part 73, Physical Protection of Plants and Materials*

The proposed rule would amend § 73.1(b) to clarify that the regulations in 10 CFR Part 73 also apply to licenses issued under 10 CFR Part 52.

#### *I. 10 CFR Part 140, Financial Protection Requirements and Indemnity Agreements*

The proposed rule would amend §§ 140.2, 140.10, 140.11, and 140.13 to correct the language to note that holders of combined licenses issued under 10 CFR Part 52 are required to conform with the Commission's financial protection requirements implementing the Price-Anderson Act (Section 170 of the Atomic Energy Act of 1954). The proposed rule would also add new §§ 140.11(c) and 140.13(b). Paragraph 140.11(c) would specify that a holder of a combined license must have and maintain financial protection when the Commission authorizes operation under § 52.231(g). Paragraph 140.13(b) would require that each holder of a combined license who is also the holder of a license under 10 CFR Part 70 authorizing ownership, possession, and storage only of special nuclear material at the site of the nuclear reactor have and maintain financial protection in the amount of \$1,000,000. Proof of financial protection would be required to be filed with the Commission in the manner specified prior to issuance of the license under 10 CFR Part 70.

*J. 10 CFR Part 170, Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended*

The proposed rule would amend § 170.2 to clarify the applicability of the regulations in 10 CFR Part 170 to the licensing processes in 10 CFR Parts 50 and 52.

IV. Specific Requests for Comments

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

1. Should the final rule include an updating requirement for other than emergency preparedness information and what portions of the early site permit (ESP) should be subject to the updating requirement? Also, if an updating requirement is adopted, in what manner could an interested person challenge the updated information? (refer to § 52.39(a))

2. Should the final rule include revisions to 10 CFR Part 52 to: (1) distinguish between site characteristics, site parameters, and design parameters; (2) require the Commission to specify the site parameters and design parameters when issuing early site permits; (3) require the design certification rule to specify the site parameters and design parameters for the design; (3) require a combined license applicant referencing an early site permit to demonstrate that either the design of the nuclear power plant or the site parameters and design parameters of a referenced design certification rule, fall within/meet the design and site parameters of the early site permit; and (4) require a combined license applicant referencing a design certification rule to demonstrate that the site parameters and design parameters of the design certification rule fall within/meet either: (i) the site characteristics of a site, or (ii) the site parameters and design parameters of a referenced early site permit.

3. Are there terms and conditions for an ESP that can only be fulfilled after issuance of the referencing combined license, such that “have been met” should be changed to “will be met,” or “have been and will be met”? (refer to proposed § 52.211(a)(1))

4. Should the final rule include a requirement in § 50.34(a) for a construction permit application that references an ESP to demonstrate that the design of the facility falls within the site parameters of the ESP? (refer to proposed § 52.211(a)(1))

5. Should the final rule include a requirement in 10 CFR Part 50 to perform testing to qualify advanced reactor designs before licensing? The purpose of this testing requirement would be to demonstrate that new or innovative safety features will perform as predicted in an applicant's safety analysis report, that effects of systems interactions have been found acceptable, and to provide sufficient data for analytical code validation, as required by proposed §§ 52.107(b) and 52.211(b).

6. Should the final rule include a revision to the current § 52.63 (proposed § 52.127) to allow the original design certification applicant to petition the Commission for rulemaking to amend the design certification rule to incorporate "beneficial changes," including improvements in safety, and/or design changes that would "significantly improve efficiency, reliability and economics." Refer to letters from Steven A. Hucik, GE Nuclear Energy (March 30, 2002) and Ronald L. Simard, Nuclear Energy Institute (March 22, 2002).

7. Should 10 CFR Part 21 apply to: (a) a holder of an early site permit, but only after the holder references the permit in a license application, and (b) an applicant/vendor of a design which is the subject of a design certification rule, but only after the design certification rule is first referenced in a license application. In both cases, the Commission believes that there is no reasonable possibility of a "substantial safety hazard" until either the early site permit or design certification rule is referenced. The Commission seeks public comment on the Commission's proposed basis for this proposal, and whether there are other factors and policy considerations, either in support of, or in opposition to, the Commission's proposal.

## V. Availability of Documents

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

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

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

NRC's Public Electronic Reading Room (PERR). The NRC's public electronic reading room is located at [www.nrc.gov/reading-rm.html](http://www.nrc.gov/reading-rm.html).

<b>Document</b>	<b>PDR</b>	<b>Web</b>	<b>PERR</b>
Comments on the draft rule language			
General Electric	X	X	ML013180207
Entergy	X	X	ML013200006
Nuclear Energy Institute	X	X	ML013200158
Westinghouse	X	X	ML013200173
Exelon	X	X	ML020040187
Regulatory History of Design Certification <sup>6</sup>	X		ML003761550

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<sup>6</sup>The regulatory history of the NRC's design certification reviews is a package of 100 documents that is available in NRC's PERR and in the PDR. This history spans a 15-year period during which the NRC simultaneously developed the regulatory standards for reviewing these designs and the form and content of the rules that certified the designs.

## VI. Plain Language

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

## VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this proposed rule, the NRC is revising the procedural requirements for early site permits, standard design certifications, and combined licenses for nuclear power plants to make certain corrections and changes based on the experience of the previous design certification reviews and on discussions with stakeholders on these licensing processes. In addition, this proposed rule would amend certain portions of the three design certification rules in 10 CFR Part 52, Appendices A, B, and C (for U.S. ABWR, System 80+, and AP600 designs, respectively) Design certifications are not generic rulemakings in the sense that design certifications do not establish standards or requirements with which all licensees must comply. Rather, design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certification rulemakings are initiated by an applicant for a design certification, rather than the NRC. For

these reasons, the Commission concludes that this action does not constitute the establishment of a standard that contains generally applicable requirements.

#### VIII. Environmental Impact: Categorical Exclusion

The NRC has determined that the changes made in this proposed rule fall within the types of action described in categorical exclusions 10 CFR 51.22(c)(1), (c)(2), and (c)(3).

Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.<sup>7</sup>

#### IX. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements contained in 10 CFR Part 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150–0151. The proposed changes to 10 CFR Parts 2, 20, 21, 50, 51, 72, 73, 140, 170, and 171 do not contain new or amended information collection requirements. Existing requirements were approved by the Office of Management and Budget, approval numbers 3150-0014, 3150-0035, 3150-0011, 3150-0021, 3150-0132, 3150-0002, and 3150-0039.

The burden to the public for the information collections in 10 CFR Part 52 is estimated to average 3,308 hours per response. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment

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<sup>7</sup>When 10 CFR Part 52 was promulgated in 1989, the NRC determined that the regulation met the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(3). As stated in the *Federal Register* notice for the final rule (54 FR 15384, April 18, 1989), “It makes no substantive difference for the purpose of the categorical exclusion that the amendments are in a new 10 CFR Part 52 rather than in 10 CFR Part 50. The amendments are, in fact, amendments to the 10 CFR Part 50 procedures and could have been placed in that part.” The categorical exclusion for the current proposed change to 10 CFR Part 52 is consistent with the original categorical exclusion determination.

on the potential impact of the information collections contained in the proposed rule and on the following issues:

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

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0151), Office of Management and Budget, Washington, DC 20503.

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

#### X. Public Protection Notification

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

#### XI. Regulatory Analysis

The Commission has prepared the following draft regulatory analysis on the substantive changes in this proposed regulation that could impose regulatory burdens. The majority of the

changes in this proposed rule involve formatting, reorganization, or process changes that do not affect regulatory burden. These types of changes are not addressed in this regulatory analysis, as they would not affect the burden on future applicants.

The proposed rule contains two amendments that appear to impose regulatory burdens on future applicants for construction permits, combined licenses, and duplicate design licenses who may file an application referencing an early site permit or a certified design. There are no current applicants who would be burdened by the proposed amendments.

The first of these changes requires applicants who reference an early site permit to update and correct emergency planning information and discuss whether the new information materially alters the bases for compliance with the applicable requirements. The second change requires applicants who reference a certified design to include a plant-specific probabilistic risk assessment (PRA) that uses the design-specific PRA and is updated to account for site-specific design information and any design changes.

The Commission believes that, practically speaking, there would be no change in the burden on future applicants resulting from these amendments. This is because the information required by the proposed rule would, in all likelihood, be requested by the NRC staff during the review of the application if these requirements were not adopted. The staff could not perform an adequate review of an application referencing an early site permit without reviewing the most up-to-date emergency planning information. Therefore, if this updated information was not required in the application, the staff would be compelled to request the information from the applicant in order to make a finding that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Likewise, if the Commission did not require an updated PRA in an application for a combined license referencing a certified design, the staff would be compelled to request the information from the applicant. The Commission would need this information in order to assist it

in finding that the applicable requirements of 10 CFR Part 50 have been met, and in developing the inspections, tests, and analyses that the licensee must perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Atomic Energy Act, and the Commission's rules and regulations.

For these reasons, the Commission believes it is prudent to proceed with this proposed rulemaking. The addition of these requirements for applicants for construction permits, combined licenses, and duplicate design licenses is necessary to ensure the NRC staff can meet its regulatory obligations. In addition, giving future applicants notification up front that the staff requires this information in the application will relieve them of a larger burden of having to compile the information during the application review process when the Commission requests the information to complete its review. The need to compile the information during the review process could impact the review schedule and result in other unnecessary burdens on the applicant.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

## XII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing of nuclear power plants. The companies that will apply for an approval, certification, permit, site report, or license in accordance with the regulations affected by this proposed rule do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

### XIII. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109. The proposed rule would revise the requirements for early site permits, standard design certifications, and combined licenses for nuclear power plants, so it would affect a potential applicant who might, in the future, apply for an early site permit, design certification, or combined license. However, the backfit rule does not apply because the proposed rule would not impose any modifications on a current holder or an early site permit, certified design, or combined license.

#### List of Subjects

##### 10 CFR Part 2

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

##### 10 CFR Part 20

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

##### 10 CFR Part 21

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

##### 10 CFR Part 50

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

10 CFR Part 51

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

10 CFR Part 52

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

10 CFR Part 72

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

10 CFR Part 73

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

10 CFR Part 140

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

10 CFR Part 170

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 2, 20, 21, 50, 51, 52, 72, 73, 140, and 170.

## PART 2 - RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

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

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

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97-425, 96 Stat. 2213, as amended (42 U.S.C. 10143(f)); sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183i, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948-951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Section 2.205(j) also issued under Pub. L. 101-410, 104 Stat. 90, as amended by section 3100(s), Pub. L. 104-134, 110 Stat. 1321-373 (28 U.S.C. 2461 note). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332).

Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133), and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553, and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart M also issued under sec. 184 (42 U.S.C. 2234) and sec. 189, 68 stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91-560, 84 Stat. 1473 (42 U.S.C. 2135).

2. In § 2.110, paragraph (a) is revised to read as follows:

§2.110 Filing and administrative action on submittals for design review or early review of site suitability issues.

(a)(1) A submittal under Subpart E of Part 52 of this chapter must be subject to §§2.101(a) and 2.790 to the same extent as if it were an application for a permit or license.

(2) Except as specifically provided otherwise by the provisions of Subpart B to Part 52 of this chapter, a submittal under Subpart B must be subject to §2.101(a) (2) through (4) to the same extent as if it were an application for a permit or license.

\* \* \* \* \*

3. Section 2.400 is revised to read as follows:

§2.400 Scope of subpart.

This subpart describes procedures applicable to licensing proceedings that involve the consideration in hearings of a number of applications, filed by one or more applicants pursuant to Subpart I of Part 52 of this chapter, for licenses to construct and operate nuclear power reactors of essentially the same design to be located at different sites.

4. Section 2.401 is revised to read as follows:

§2.401 Notice of hearing on applications under Subpart I of Part 52 for construction permits.

(a) In the case of applications under Subpart I of Part 52 of this chapter for construction permits for nuclear power reactors of the type described in §50.22 of this chapter, the Secretary will issue notices of hearing under §2.104.

(b) The notice of hearing will also state the time and place of the hearings on any separate phase of the proceeding.

5. In § 2.402, paragraph (a) is revised to read as follows:

§2.402 Separate hearings on separate issues; consolidation of proceedings.

(a) In the case of applications pursuant to Subpart I of Part 52 of this chapter for construction permits for nuclear power reactors of a type described in §50.22 of this chapter, the Commission or the presiding officer may order separate hearings on particular phases of the proceeding, such as matters related to the acceptability of the design of the reactor, in the context of the site parameters postulated for the design; environmental matters; or antitrust aspects of the application.

\* \* \* \* \*

6. Section 2.403 is revised to read as follows:

§2.403 Notice of proposed action on applications for operating licenses pursuant to Subpart I of Part 52.

In the case of applications under Subpart I of Part 52 of this chapter for operating licenses for nuclear power reactors, if the Commission has not found that a hearing is in the public interest, the Director of Nuclear Reactor Regulation will, prior to acting thereon, cause to be published in the *Federal Register*, under §2.105, a notice of proposed action with respect to each application as soon as practicable after the applications have been docketed.

7. Section 2.404 is revised to read as follows:

§2.404 Hearings on applications for operating licenses under Subpart I of Part 52.

If a request for a hearing and/or petition for leave to intervene is filed within the time prescribed in the notice of proposed action on an application for an operating license under Subpart I of Part 52 of this chapter with respect to a specific reactor(s) at a specific site and the Commission or an atomic safety and licensing board designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel has issued a notice of hearing or other appropriate order, the Commission or the atomic safety and licensing board may order separate hearings on particular phases of the proceeding and/or consolidate for hearing two or more proceedings in the manner described in §2.402.

8. Section 2.406 is revised to read as follows:

§2.406 Finality of decisions on separate issues.

Notwithstanding any other provision of this chapter, in a proceeding conducted under this subpart and Subpart I of Part 52 of this chapter, no matter which has been reserved for consideration in one phase of the hearing shall be considered at another phase of the hearing except on the basis of significant new information that substantially affects the conclusion(s) reached at the other phase or other good cause.

9. Section 2.500 is revised to read as follows:

§2.500 Scope of subpart.

This subpart prescribes procedures applicable to licensing proceedings which involve the consideration in separate hearings of an application for a license to manufacture nuclear power reactors under Subpart H of Part 52 of this chapter, and applications for construction permits and operating licenses for nuclear power reactors which have been the subject of such an application for a license to manufacture such facilities (manufacturing license).

10. In § 2.501, paragraphs (a), (b)(1)(vii) and (b)(3) are revised to read as follows:

§2.501 Notice of hearing on application under Subpart H of Part 52 for a license to manufacture nuclear power reactors.

(a) In the case of an application under Subpart H of Part 52 of this chapter for a license to manufacture nuclear power reactors of the type described in §50.22 of this chapter to be operated at sites not identified in the license application, the Secretary shall issue a notice of hearing to be published in the *Federal Register* at least thirty (30) days prior to the date set for hearing in the notice. The notice must be issued as soon as practicable after the application has been docketed. The notice will state:

- (1) The time, place, and nature of the hearing and/or the prehearing conference;
- (2) The authority within which the hearing is to be held;
- (3) The matters of fact and law to be considered; and
- (4) The time within which answers to the notice shall be filed.

(b) \* \* \*

(1) \* \* \*

(vii) Whether, in accordance with the requirements of Subpart A of Part 51 and Subpart H of Part 52 of this chapter, the license should be issued as proposed.

\* \* \* \* \*

(3) That, regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with Subpart A of Part 51 and § 52.245(b) of this chapter,

\* \* \* \* \*

11. Section 2.502 is revised to read as follows:

§2.502 Notice of hearing on application for a permit to construct a nuclear power reactor manufactured under a Commission license issued under Subpart H of Part 52 of this chapter at the site at which the reactor is to be operated.

The issues stated for consideration in the notice of hearing on an application for a permit to construct a nuclear power reactor(s) which is the subject of an application for a manufacturing license under Subpart H of Part 52 of this chapter, will be those stated in §2.104(b) and, in addition, whether the site on which the facility is to be operated falls within the postulated site parameters specified in the relevant application for a manufacturing license.

#### PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

12. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

13. Section 20.1002 is revised to read as follows:

##### § 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under Parts 30 through 36, 39, 40, 50, 52, 60, 61, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under Part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 10 CFR 35.75, or to exposure from voluntary participation in medical research programs.

#### PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

14. The authority citation for Part 21 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C. 2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5846).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97 - 425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

15. In § 21.2, paragraphs (a), (b), and (c) are revised to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or Part 72 of this chapter, to:

(1) Each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and each director and responsible officer of such a licensee; and

(2) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such organization, that holds a permit or license under Part 52 of this chapter or constructs a production or utilization facility licensed for the manufacture, construction, or operation pursuant to Part 50 or Part 52 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to Part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste pursuant to Part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under Part 60 or 63 of this

chapter; or supplies basic components for a facility or activity licensed, other than for export, under Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or Part 72 of this chapter.

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 of this chapter or a combined license issued under § 52.227 of this chapter, or approved to hold a permit for a site or sites for one or more nuclear power facilities under § 52.24 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under §50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under Part 50 or Part 52 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§50.72, 50.73 or §73.71 of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

\* \* \* \* \*

16. Section 21.3 is revised to read as follows:

§ 21.3 Definitions.

As used in this part:

*Basic component.* (a)(1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 or Part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

- (i) The integrity of the reactor coolant pressure boundary;
- (ii) The capability to shut down the reactor and maintain it in a safe shutdown condition;

or

(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(2) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR Part 50, appendix B, or commercial grade items which have successfully completed the dedication process.

(b) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(c) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

*Commercial grade item.* (a) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 or Part 52, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic

component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(b) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:

(1) Not subject to design or specification requirements that are unique to those facilities or activities;

(2) Used in applications other than those facilities or activities; and

(3) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

*Commission* means the Nuclear Regulatory Commission or its duly authorized representatives.

*Constructing or construction* means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

*Critical characteristics.* When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 or Part 52, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

*Dedicating entity.* When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 or Part 52, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

*Dedication.* (a) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 or Part 52, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third- party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(b) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

*Defect* means: (a) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or

(b) The installation, use, or operation of a basic component containing a defect as defined in this section; or

(c) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 or Part 52 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(d) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to Part 50 or Part 52 of this chapter.

*Deviation* means a departure from the technical requirements included in a procurement document.

*Director* means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, director means the individual.

*Discovery* means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21(a).

*Evaluation* means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

*Notification* means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

*Operating or operation* means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety related.

*Procurement document* means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

*Responsible officer* means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

*Substantial safety hazard* means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

*Supplying or supplies* means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

17. Section 21.21 is revised to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to--

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(d)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in § 21.21(a)(1) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity--

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect.

(b) If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).

(c) A dedicating entity is responsible for--

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

(d)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting--

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under paragraph (d)(1) of this section and the evaluation of a failure to comply or a deviation under paragraph (a)(1) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

(3) Notification required by paragraph (d)(1) of this section must be made as follows--

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816-5151 or by telephone at (301) 816-5100 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.

(4) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(5) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(e) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

#### PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

18. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

19. In § 50.109, paragraph (a)(1) is revised to read as follows:

§ 50.109 Backfitting.

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position after:

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985; or

(ii) Six months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985; or

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses; or

(iv) The date of issuance of the design approval under Subpart E of Part 52 of this chapter;

(v) The date of issuance of a manufacturing license under Subpart H of Part 52 of this chapter;

(vi) The date of issuance of the first construction permit issued for a duplicate design under Subpart I of Part 52 of this chapter; or

(vii) The date of issuance of a combined license under Subpart G of Part 52 of this chapter, provided that if the combined license references an early site permit, the provisions in § 52.39 apply with respect to the site characteristics, terms, and conditions of the early site permit.

If the combined license references an early site review, the provisions in § 52.47 apply with respect to the staff site report. If the combined license references a design certification rule, the provisions in § 52.127(a) apply with respect to the design matters resolved in the design certification.

\* \* \* \* \*

PART 51 - ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING  
AND RELATED REGULATORY FUNCTIONS

20. The authority citation for Part 51 continues to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953, (42 U.S.C. 2201, 2297f); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842). Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853-854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95-604, Title II, 92 Stat. 3033-3041; and sec. 193, Pub. L. 101-575, 104 Stat. 2835 (42 U.S.C. 2243). Sections 51.20, 51.30, 51.60, 51.80. and 51.97 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241, and sec. 148, Pub. L. 100-203, 101 Stat. 1330-223 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036-3038 (42 U.S.C. 2021) and under Nuclear Waste Policy Act of 1982, sec. 121, 96 Stat. 2228 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also under Nuclear Waste Policy Act of 1982, sec. 114(f), 96 Stat. 2216, as amended (42 U.S.C. 10134(f)).

21. In § 51.20, paragraph (b)(6) is revised to read as follows:

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

\* \* \* \* \*

(b) \* \* \*

(6) Issuance of a license to manufacture pursuant to Subpart H of Part 52 of this chapter.

\* \* \* \* \*

22. Part 52 is revised to read as follows:

## PART 52 – ADDITIONAL LICENSING PROCESSES FOR NUCLEAR POWER PLANTS

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APPENDIX A - Design Certification Rule for the U.S. Advanced Boiling Water Reactor

APPENDIX B - Design Certification Rule for the System 80+ Design

APPENDIX C - Design Certification Rule for the AP600 Design

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2133, 2201, 2232, 2233,

2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

## General Provisions

### § 52.1 Scope.

This part governs the issuance of early site permits and staff site reports, design approvals and certifications, and combined, manufacturing, and duplicate design licenses for nuclear power facilities licensed under Section 103 or 104b of the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). This part also gives notice to all persons who knowingly provide to any licensee, holder of, or applicant for an approval, certification, permit, site report, or license, or to a contractor, subcontractor, or consultant of any of them, components, equipment, materials, or other goods or services, that relate to the activities of a licensee, holder of, or applicant for an approval, certification, permit, site report, or license, subject to this part, that they may be individually subject to NRC enforcement action for violation of the provisions in 10 CFR 50.5.

### § 52.3 Definitions.

(a) As used in this part - -

Combined license means a combined construction permit and operating license with conditions for a nuclear power facility issued pursuant to Subpart C of this Part.

Early site permit means a Commission approval, issued pursuant to Subpart A of this part, for a site or sites for one or more nuclear power facilities.

Modular design means a nuclear power station that consists of two or more essentially identical nuclear reactors (modules), where each module is a separate nuclear reactor capable of being safely operated independent of the state of completion or operating condition of any

other module co-located on the same site, even though the nuclear power station may have some shared or common systems.

Prototype plant means a nuclear reactor that is used to test design features, such as the testing required by § 52.107(b)(2). The prototype plant is similar to the first-of-a-kind or standard plant design in all features and size, but may include additional safety features to protect the public, the plant staff, and the plant itself from the possible consequences of accidents during the testing period.

Standard design means a design which is sufficiently detailed and complete to support certification in accordance with Subpart B of this part, and which is usable for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

Standard design certification, design certification, or certification means a Commission approval, issued pursuant to Subpart B of this part, of a standard design for a nuclear power facility. A design so approved may be referred to as a *certified standard design*.

(b) All other terms in this part have the meaning set out in 10 CFR 50.2, or Section 11 of the Atomic Energy Act, as applicable.

#### § 52.5 Applicability of 10 CFR Part 50 provisions.

Unless otherwise specifically provided for in this part, §§ 50.3, 50.4, 50.5, 50.7, 50.9, 50.10, 50.11, 50.12, 50.13, 50.50, 50.51, 50.52, 50.53, 50.54, 50.55, 50.55a, 50.56, 50.57, 50.58, 50.59, 50.70, 50.71, 50.72, 50.73, 50.74, 50.75, 50.78, 50.80, 50.81, 50.82, 50.90, 50.91, 50.92, 50.100, 50.101, 50.102, 50.103 and 50.109 of this chapter apply to a licensee, holder of, or applicant for an approval, certification, permit, site report, or license issued under this part. A licensee, holder of, or applicant for an approval, certification, permit, site report, or license

issued under this part shall comply with all requirements in these provisions that are otherwise applicable to applicants or licensees under Part 50 of this chapter.

§ 52.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under Control Number 3150-0151.

(b) The approved information collection requirements contained in this part appear in §§52.15, 52.17, 52.19, 52.29, 52.35, 52.39, 52.43, 52.105, 52.107, 52.121, 52.127, 52.133, 52.135, 52.203, 52.205, 52.207, 52.209, 52.211, 52.223, 52.225, 52.229, 52.231, 52.245, 52.249, 52.265, and Appendices A, B, and C.

Subpart A – Early Site Permits

§ 52.11 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of early site permits for approval of a site or sites for one or more nuclear power facilities separate from the filing of an application for a construction permit, combined license, or duplicate design license for such a facility.

§ 52.13 Relationship to Subpart F of 10 CFR Part 2 and Subpart B of this part.

The procedures of this subpart do not replace those set out in Subpart F of 10 CFR Part 2 or Subpart B of this part. Subpart F of 10 CFR Part 2 applies only when an early partial decision of site suitability issues is sought in connection with an application for a permit to

construct certain power facilities. Subpart B applies only when NRC staff review of one or more site suitability issues is sought separately from and prior to the submittal of an application for a construction permit, combined license, or duplicate design license. A Staff Site Report issued under Subpart B in no way affects the authority of the Commission or the presiding officer in any proceeding under Subparts F or G of 10 CFR Part 2. Subpart A applies when any person who may apply for a construction permit under 10 CFR Part 50 or for a combined license under Part 52 seeks an early site permit from the Commission separately from an application for a construction permit or a combined license for a facility.

§ 52.15 Filing of applications.

(a) Any person who may apply for a construction permit under 10 CFR Part 50, or for a combined license under this part, may file an application for an early site permit with the Director of Nuclear Reactor Regulation. An application for an early site permit may be filed notwithstanding the fact that an application for a construction permit or a combined license has not been filed in connection with the site or sites for which a permit is sought.

(b) The application must comply with the filing requirements of 10 CFR 50.30 (a), (b), and (f) as they would apply to an application for a construction permit. The following portions of 10 CFR 50.4, which is referenced by 10 CFR 50.30(a)(1), are applicable: paragraphs (a), (b) (1) (2) (3), (c), (d), and (e).

(c) The fees associated with the filing and review of an application for the initial issuance or renewal of an early site permit are set forth in 10 CFR Part 170.

§ 52.17 Contents of applications.

(a)(1) The application must contain the information required by 10 CFR 50.33 (a) through (d), the information required by 10 CFR 50.34 (a)(12) and (b)(10), and to the extent

approval of emergency plans is sought under paragraph (b)(2)(ii) of this section, the information required by § 50.33 (g) and (j), and § 50.34 (b)(6)(v) of this chapter. The application must also contain a description and safety assessment of the site on which the facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in § 50.34(a)(1) of this chapter. Site characteristics must comply with Part 100 of this chapter. In addition, the application should describe the following:

- (i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;
  - (ii) The boundaries of the site;
  - (iii) The proposed general location of each facility on the site;
  - (iv) The anticipated maximum levels of radiological and thermal effluents each facility will produce;
  - (v) The type of cooling systems, intakes, and outflows that may be associated with each facility;
  - (vi) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site;
  - (vii) The location and description of any nearby industrial, military, or transportation facilities and routes; and
  - (viii) The existing and projected future population profile of the area surrounding the site.
- (2) A complete environmental report as required by 10 CFR 51.45 and 51.50 must be included in the application, provided, however, that such environmental report must focus on the

environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the postulated site parameters, and provided further that the report need not include an assessment of the benefits (for example, need for power) of the proposed action, but must include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed.

(b) (1) The application must identify physical characteristics unique to the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans.

(2) The application may also either:

(i) Propose major features of the emergency plans, such as the exact sizes of the emergency planning zones, that can be reviewed and approved by NRC in consultation with FEMA in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans for review and approval by the NRC, in consultation with the Federal Emergency Management Agency, in accord with the applicable provisions of 10 CFR 50.47.

(3) Under paragraphs (b)(1) and (b)(2)(i) of this section, the application must include a description of contacts and arrangements made with local, state, and Federal governmental agencies with emergency planning responsibilities.

(i) Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant shall make good faith efforts to obtain from the same governmental agencies certifications that:

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii) The application must contain any certifications that have been obtained. If these certifications cannot be obtained, the application must contain information, including a utility plan, sufficient to show that the proposed plans nonetheless provide reasonable assurance that adequate protective measures can and will be taken, in the event of a radiological emergency at the site.

(c) If the applicant wishes to be able to perform, after grant of the early site permit, the activities at the site allowed by 10 CFR 50.10(e)(1) without first obtaining the separate authorization required by that section, the applicant shall propose, in the early site permit, a plan for redress of the site in the event that the activities are performed and the site permit expires before it is referenced in an application for a construction permit or a combined license issued under Subpart G of this part. The application must demonstrate that there is reasonable assurance that redress carried out under the plan will achieve an environmentally stable and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

§ 52.18 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the applicable standards set out in 10 CFR Part 50 and its appendices and 10 CFR Part 100 as they apply to applications for construction permits for nuclear power plants. In particular, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR Part 51, provided, however, that the draft and final environmental impact statements prepared by the Commission focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall

within the postulated site parameters, and provided further that the statements need not include an assessment of the benefits (for example, need for power) of the proposed action, but must include an evaluation of alternative sites to determine whether there is any obviously superior alternative to the site proposed. The Commission shall determine, after consultation with the Federal Emergency Management Agency, whether the information required of the applicant by § 52.17(b)(1) shows that there is no significant impediment to the development of emergency plans, whether any major features of emergency plans submitted by the applicant under § 52.17(b)(2)(i) are acceptable, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

§ 52.19 Applicability of NRC requirements.

(a) An applicant shall comply with all requirements in 10 CFR Chapter I applicable to applicants for construction permits and limited work authorizations under 10 CFR 50.10.

(b) A holder of an early site permit shall comply with all requirements in 10 CFR Chapter I applicable to holders of construction permits and limited work authorizations under 10 CFR 50.10.

§ 52.21 Hearings.

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, including the requirements for docketing in 10 CFR 2.101(a)(1) - (4), and the requirements for issuance of a notice of hearing in 10 CFR 2.104(a), (b)(1)(iv) and (v), (b)(2) to the extent it runs parallel to § 2.104(b)(1)(iv) and (v), and (b)(3). However, the designated sections may not be construed to require that the environmental report or draft or final environmental impact statement include an assessment of the benefits of the proposed action. In the hearing, the presiding officer shall

also determine whether, taking into consideration the site criteria contained in 10 CFR Part 100, a reactor, or reactors, having characteristics that fall within the parameters for the site can be constructed and operated without undue risk to the health and safety of the public. All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in Subpart G of 10 CFR Part 2.

§ 52.23 Referral to the ACRS.

The Commission shall refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety.

§ 52.24 Issuance of early site permit.

After conducting a hearing under § 52.21 of this subpart and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 52.23 of this subpart, and upon determining that an application for an early site permit meets the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made, the Commission shall issue an early site permit, in the form the Commission deems appropriate and necessary. The early site permit shall specify the site parameters and the terms and conditions of the early site permit.

§ 52.25 Extent of activities permitted.

(a) If an early site permit contains a site redress plan, the holder of the permit, or the applicant for a construction permit or a combined license who references the permit, may perform the activities at the site allowed by 10 CFR 50.10(e)(1) without first obtaining the separate authorization required by that section, if the final environmental impact statement

prepared for the permit has concluded that the activities will not result in any significant adverse environmental impact which cannot be redressed.

(b) If the activities permitted by paragraph (a) of this section are performed at any site for which an early site permit has been granted, and the site is not referenced in an application for a construction permit or a combined license issued under Subpart G of this part while the permit remains valid, then the early site permit must remain in effect solely for the purpose of site redress, and the holder of the permit shall redress the site in accordance with the terms of the site redress plan required by 10 CFR 52.17(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 52.27 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than ten nor more than twenty years from the date of issuance.

(b)(1) An early site permit continues to be valid beyond the date of expiration in any proceeding on a construction permit application or a combined license application that references the early site permit and is docketed either before the date of expiration of the early site permit, or, if a timely application for renewal of the permit has been filed, before the Commission has determined whether to renew the permit.

(2) An early site permit also continues to be valid beyond the date of expiration in any proceeding on an operating license application which is based on a construction permit that references the early site permit, and in any hearing held under 10 CFR 52.231 before operation begins under a combined license which references the early site permit.

(c) An applicant for a construction permit or combined license may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

§ 52.28 Transfer of early site permit.

An application to transfer an early site permit will be processed under 10 CFR 50.80.

§ 52.29 Application for renewal.

(a) Not less than twelve nor more than thirty-six months prior to the end of the initial twenty-year period, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR 2.714. If a hearing is granted, notice of the hearing will be published in accordance with 10 CFR 2.703.

(c) An early site permit, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in certain proceedings in accordance with the provisions of § 52.27(b).

(d) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.31.

§ 52.31 Criteria for renewal.

(a) The Commission shall grant the renewal if the Commission determines that the site complies with:

(1) The Atomic Energy Act and the Commission's regulations and orders applicable and in effect at the time the site permit was originally issued;

(2) Any new requirements the Commission may wish to impose after a determination that there is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements; and

(3) The direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal on this basis does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.

#### § 52.33 Duration of renewal.

Each renewal of an early site permit may be for not less than ten nor more than twenty years.

#### § 52.35 Use of site for other purposes.

A site for which an early site permit has been issued under this subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder shall inform the Director of Nuclear Reactor Regulation of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, in accordance with the provisions of § 52.39. If

the permit holder informs the Director that the holder no longer intends to use the site for a nuclear power plant, the Director shall terminate the permit.

§ 52.37 Reporting of defects and noncompliance; revocation, suspension, modification of permits for cause.

For purposes of 10 CFR Part 21 and 10 CFR 50.100, an early site permit is a construction permit.

§ 52.39 Finality of early site permit determinations.

(a)(1) Notwithstanding any provision in 10 CFR 50.109, while an early site permit is in effect under §§ 52.27 or 52.33, the Commission may not change or impose new site characteristics, terms or conditions of the early site permit, including emergency planning requirements, on the early site permit or the site for which it was issued, unless the Commission determines that a modification is necessary either to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued, or to assure adequate protection of the public health and safety or the common defense and security.

(2) In making the findings required for issuance of a construction permit, operating license, combined license, or duplicate design license, or the findings required by § 52.231 of this part, if the application for the construction permit, operating license, combined license, or duplicate design license references an early site permit, the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit (with the exception of the matters in paragraph (b) of this section), unless a contention is admitted that a nuclear reactor does not fit within one or more of the site parameters in the early site permit, or a petition is filed which alleges either that the site does not

conform to the site characteristics in the early site permit, or that the terms and conditions of the early site permit should be modified.

(i) A contention that a nuclear reactor does not fit within one or more of the site parameters included in the site permit may be litigated in the same manner as other issues material to the proceeding.

(ii) A petition which alleges that the site does not conform to the site characteristics in the early site permit must include, or clearly reference, official NRC documents, documents prepared by or for the permit holder, or evidence admissible in a proceeding under Subpart G of Part 2 of this chapter, which show, prima facie, that the site does not conform to the site characteristics. The permit holder and NRC staff may file answers to the petition within the time specified in 10 CFR 2.730 for answers to motions by parties and staff. If the Commission, in its judgment, decides, on the basis of the petitions and any answers thereto, that the petition meets the requirements of this paragraph, that the issues are not exempt from adjudication under 5 U.S.C. 554(a)(3), that genuine issues of material fact are raised, and that settlement or other informal resolution of the issues is not possible, then the genuine issues of material fact raised by the petition must be resolved in accordance with the provisions in 5 U.S.C. §§ 554, 556, and 557 which are applicable to determining application for initial licenses.

(iii) A petition which alleges that the terms and conditions of the early site permit should be modified will be processed in accordance with 10 CFR 2.206. Before construction commences, the Commission shall consider the petition and determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Construction under the construction permit or combined license will not be affected by the granting of the petition unless the order is made immediately effective.

(iv) Prior to construction, the Commission shall find that the terms and conditions of the early site permit have been met.

(b) An applicant for a construction permit, duplicate design license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update and correct the information that was provided under § 52.17(b), and discuss whether the new information materially changes the bases for compliance with the applicable requirements. New information which materially changes the bases for the Commission's determination on the matters in § 52.17(b) must be subject to litigation during the construction permit, operating license, or combined license proceeding in the same manner as other issues material to those proceedings.

(c) An applicant for a construction permit, an operating license, or a combined license who has filed an application referencing an early site permit issued under this subpart may include in the application a request for a variance from one or more elements of the permit. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Issuance of the variance must be subject to litigation during the construction permit, operating license, or combined license proceeding in the same manner as other issues material to those proceedings.

#### Subpart B – Early Site Reviews

##### § 52.41 Scope of subpart.

This subpart sets out procedures for the filing, staff review, and referral to the Advisory Committee on Reactor Safeguards (ACRS) of requests for early review of one or more site suitability issues relating to the construction and operation of certain utilization facilities separately from and prior to the submittal of applications for construction permits, combined

licenses, or duplicate design licenses for the facilities. The subpart also sets out procedures for the preparation and issuance of Staff Site Reports and for their incorporation by reference in applications for the construction and operation of certain utilization facilities. The utilization facilities are those which are subject to § 51.20(b) of this chapter and are of the type specified in § 50.21(b)(2) or (3) or § 50.22 of this chapter or are testing facilities. This subpart does not apply to proceedings conducted pursuant to Subpart F of Part 2 of this chapter.

§ 52.43 Filing and contents of applications.

(a) Any person may submit information regarding one or more site suitability issues to the Commission's Staff for its review separately from and prior to an application for a construction permit, a combined license, or a duplicate design license for a facility. The submittal must consist of the portion of the information required of applicants for construction permits by §§ 50.33 (a) through (c) and (e) of this chapter, and, insofar as it relates to the issue(s) of site suitability for which early review is sought, by §§ 50.34(a)(1) and 50.30(f) of this chapter. Information with respect to operation of the facility at the projected initial power level need not be supplied.

(b) The submittal for early review of site suitability issue(s) must be made in the same manner and in the same number of copies as provided in §§ 50.4 and 50.30 of this chapter for license applications. The submittal must include sufficient information concerning the range of postulated facility design and operation parameters to enable the NRC staff to perform the requested review of site suitability issues. The submittal must contain suggested conclusions on the issues of site suitability submitted for review and must be accompanied by a statement of the bases or the reasons for those conclusions. The submittal must also list, to the extent possible, any long-range objectives for ultimate development of the site, state whether any site selection

process was used in preparing the submittal, describe any site selection process used, and explain what consideration, if any, was given to alternative sites.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR Part 170.

§ 52.45 Notice of application.

The NRC staff shall publish a notice of docketing of the submittal in the *Federal Register*, and shall send a copy of the notice of docketing to the Governor of the State, local government bodies (county, municipality, or other political subdivision), and affected, Federally-recognized Indian Tribes. This notice must identify the location of the site, briefly describe the site suitability issue(s) under review, and invite comments from Federal, State, Tribal, and local agencies and interested persons within 120 days of publication or such other time as may be specified, for consideration by the staff in connection with the initiation or outcome of the review and, if appropriate, by the ACRS in connection with the outcome of their review. The person requesting the review shall serve a copy of the submittal on the Governor or other appropriate official of the State in which the site is located, and on the chief executive of the municipality in which the site is located or, if the site is not located in a municipality, on the chief executive of the county.

§ 52.46 Referral to the ACRS.

The portion of the submittal containing information requested of applicants for construction permits by §§ 50.33 (a) through (c) and (e) and 50.34(a)(1) of this chapter will be referred to the ACRS for a review and report. There will be no referral to the ACRS unless early review of the site safety issues under § 50.34(a)(1) is requested.

§ 52.47 Issuance of site report.

(a) Upon completion of review by the NRC staff and, if appropriate, by the ACRS of a submittal under this subpart, the NRC staff shall prepare a Staff Site Report which identifies the location of the site, states the site suitability issues reviewed, explains the nature and scope of the review, states the conclusions of the staff regarding the issues reviewed and, states the reasons for those conclusions. Upon issuance of an NRC Staff Site Report, the NRC staff shall publish a notice of the availability of the report in the *Federal Register* and shall make available a copy of the report at the NRC web site, <http://www.nrc.gov>. The NRC staff shall also send a copy of the report to the Governor of the State, local government bodies (county, municipality, or other political subdivision), and affected, Federally-recognized Indian Tribes.

(b) Any Staff Site Report prepared and issued in accordance with this subpart may be incorporated by reference, as appropriate, in an application for a construction permit, a combined license, or a duplicate design license for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specific in § 50.21(b)(2) or (3) or § 50.22 of this chapter or is a testing facility. The conclusions of the Staff Site Report will be reexamined by the staff where five years or more have elapsed between the issuance of the Staff Site Report and its incorporation by reference in an application.

(c) Issuance of a Staff Site Report does not constitute a commitment to issue a permit or license, to permit on-site work under § 50.10(e) of this chapter, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, and other presiding officers in any proceeding under 10 CFR Part 2 of this chapter.

#### § 52.49 Relationship to other subparts.

The NRC staff will not conduct more than one review of site suitability issues with regard to a particular site prior to the full construction permit, combined license, or duplicate design license review required by Subpart A of Part 51 of this chapter. The NRC staff may decline to

prepare and issue a Staff Site Report in response to a submittal under this subpart where it appears that - -

(a) In cases where no review of the relative merits of the submitted site and alternative sites under Subpart A of Part 51 of this chapter is requested, there is a reasonable likelihood that further staff review would identify one or more preferable alternative sites and the staff review of one or more site suitability issues would lead to an irreversible and irretrievable commitment of resources prior to the submittal of the analysis of alternative sites in the Environmental Report that would prejudice the later review and decision on alternative sites under Subpart F and/or G of Part 2 and Subpart A of Part 51 of this chapter; or

(b) In cases where, in the judgment of the staff, early review of any site suitability issue or issues would not be in the public interest, considering:

(1) The degree of likelihood that any early findings on those issues would retain their validity in later reviews;

(2) The objections, if any, of cognizant state or local government agencies to the conduct of an early review on those issues; and

(3) The possible effect on the public interest of having an early, if not necessarily conclusive, resolution of those issues.

Subpart C – [Reserved]

Subpart D – Standard Design Certifications

§ 52.101 Scope of subpart.

This subpart sets forth the requirements and procedures applicable to Commission issuance of rules granting standard design certification for nuclear power facilities separate from

the filing of an application for a construction permit, duplicate design license, or combined license for such a facility.

§ 52.103 Relationship to other subparts.

(a) Subpart H of this part governs the issuance of licenses to manufacture nuclear power reactors to be installed and operated at sites not identified in the manufacturing license application. Subpart I of this part governs licenses to construct and operate nuclear power reactors of duplicate design at multiple sites. These subparts may be used independently of the provisions in this subpart unless the applicant also wishes to use a certified standard design approved under this subpart.

(b) Subpart E of this part governs the NRC staff review and approval of preliminary and final standard designs. An NRC staff approval under Subpart E of this part in no way affects the authority of the Commission or the presiding officer in any proceeding under Subpart G of 10 CFR Part 2.

§ 52.105 Filing of applications.

(a)(1) Any person may seek a standard design certification for an essentially complete nuclear power plant design which is an evolutionary change from light water reactor designs of plants which have been licensed and in commercial operation before April 18, 1989.

(2) Any person may also seek a standard design certification for a nuclear power plant design which differs significantly from the light water reactor designs described in paragraph (a)(1) of this section or utilizes simplified, inherent, passive, or other innovative means to accomplish its safety functions.

(b) An application for certification may be filed notwithstanding the fact that an application for a construction permit, a duplicate design license, or a combined license for such a facility has not been filed.

(c) The applicant must comply with the filing requirements of 10 CFR 50.30(a) and 50.30(b) as these requirements would apply to an application for a nuclear power plant construction permit.

(d) The fees associated with the review of an application for the initial issuance or renewal of a standard design certification are set forth in 10 CFR Part 170.

§ 52.107 Contents of applications.

(a) The requirements of this paragraph apply to all applications for design certification.

(1) An application for design certification must contain:

(i) The technical information required of applicants for construction permits and operating licenses by 10 CFR Parts 20, 50 and its appendices, and 10 CFR Parts 73 and 100, and that is technically relevant to the design and not site-specific;

(ii) Demonstration of compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f);

(iii) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;

(iv) Proposed technical resolutions of those Unresolved Safety Issues and medium- and high-priority Generic Safety Issues that are identified in the version of NUREG-0933 current on the date six months prior to application and that are technically relevant to the design;

(v) A design-specific probabilistic risk assessment;

(vi) Proposed tests, inspections, analyses, and acceptance criteria necessary and sufficient to provide reasonable assurance that, if the tests, inspections and analyses are performed and the acceptance criteria met, a plant that references the design is built and will operate in accordance with the design certification, the provisions of the Act, and the applicable Commission's rules and regulations.

(vii) The interface requirements to be met by those portions of the plant for which the application does not seek certification. These requirements must be sufficiently detailed to allow completion of the final safety analysis and design-specific probabilistic risk assessment required by paragraph (a)(1)(v) of this section;

(viii) Justification that compliance with the interface requirements of paragraph (a)(1)(vii) of this section is verifiable through inspection, testing (either in the plant or elsewhere), or analysis. The method to be used for verification of interface requirements must be included as part of the proposed tests, inspections, analyses, and acceptance criteria required by paragraph (a)(1)(vi) of this section; and

(ix) A representative conceptual design for those portions of the plant for which the application does not seek certification, to aid the NRC staff in its review of the final safety analysis and probabilistic risk assessment required by paragraph (a)(1)(v) of this section, and to permit assessment of the adequacy of the interface requirements in paragraph (a)(1)(vii) of this section.

(2) The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design certification must include performance requirements and design information sufficiently detailed to permit the

preparation of acceptance and inspection requirements by the NRC, and procurement specifications and construction and installation specifications by an applicant. The Commission will require, prior to design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination.

(3) The NRC staff shall advise the applicant on whether any technical information beyond that required by this section must be submitted.

(b) This paragraph applies, according to its provisions, to particular applications:

(1) The application for certification of a nuclear power plant design which is an evolutionary change from light water reactor designs of plants which have been licensed and in commercial operation before April 18, 1989, must provide an essentially complete nuclear power plant design except for site-specific elements such as the service water intake structure and the ultimate heat sink.

(2) Certification of a standard design that differs significantly from the light water reactor designs described in paragraph (b)(1) of this section or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions will be granted only if

(i)(A) The performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof;

( B) Interdependent effects among the safety features of the design have been found acceptable by analysis, appropriate test programs, experience, or a combination thereof;

( C) Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions; and

( D) The scope of the design is complete except for site-specific elements such as the service water intake structure and the ultimate heat sink; or

( ii) There has been acceptable testing of a prototype plant over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. If the criterion in paragraph (b)(2)(i)(D) of this section is not met, the testing of the prototype plant must demonstrate that the non-certified portion of the plant cannot significantly affect the safe operation of the plant.

(3) An application seeking certification of a modular design must describe the various options for the configuration of the plant and site, including variations in, or sharing of, common systems, interface requirements, and system interactions. The final safety analysis and the probabilistic risk assessment should also account for differences among the various options, including any restrictions which will be necessary during the construction and startup of a given module to ensure the safe operation of any module already operating.

§ 52.109 Standards for review of applications.

Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR Parts 20, 50 and its appendices, and 10 CFR Parts 73 and 100 as they apply to applications for construction permits and operating licenses for nuclear power plants that are technically relevant to the design proposed for the facility.

§ 52.111 Applicability of NRC requirements.

An applicant shall comply with all requirements in 10 CFR Chapter I applicable to applicants for construction permits and operating licenses under 10 CFR Chapter I.

§ 52.113 Administrative review of applications.

(a) A standard design certification is a rule that will be issued in accordance with the provisions of Subpart H of 10 CFR Part 2, as supplemented by the provisions of this section. The Commission shall initiate the rulemaking after an application has been filed under this subpart and shall specify the procedures to be used for the rulemaking.

(b) The rulemaking procedures must provide for notice and comment and an opportunity for an informal hearing before an Atomic Safety and Licensing Board. The procedures for the informal hearing must include the opportunity for written presentations made under oath or affirmation and for oral presentations and questioning if the Board finds them either necessary for the creation of an adequate record or the most expeditious way to resolve controversies. Ordinarily, the questioning in the informal hearing will be done by members of the Board, using either the Board's questions or questions submitted to the Board by the parties. The Board may also request authority from the Commission to use additional procedures, such as direct and cross examination by the parties, or may request that the Commission convene a formal hearing under Subpart G of 10 CFR Part 2 on specific and substantial disputes of fact, necessary for the Commission's decision, that cannot be resolved with sufficient accuracy except in a formal hearing. The NRC staff will be a party in the hearing.

(c) The decision in such a hearing will be based only on information on which all parties have had an opportunity to comment, either in response to the notice of proposed rulemaking or in the informal hearing.

(d) Proprietary information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for construction permits and operating licenses under 10 CFR Part 50. However, the design certification is published in 10 CFR Chapter I. The provisions of 10 CFR 2.790 do not limit the protection provided under this paragraph.

§ 52.115 Referral to the ACRS.

The Commission shall refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety.

§ 52.117 Issuance of standard design certification.

After conducting a rulemaking proceeding under § 52.113 on an application for a standard design certification and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 52.115, and upon determining that the application meets the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations, the Commission shall issue a standard design certification in the form of a rule for the design which is the subject of the application.

§ 52.119 Duration of certification.

(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for fifteen years from the date of issuance.

(b) A standard design certification continues to be valid beyond the date of expiration in any proceeding on an application for a combined license or an operating license that references the standard design certification and is docketed either before the date of expiration of the certification, or, if a timely application for renewal of the certification has been filed, before the

Commission has determined whether to renew the certification. A design certification also continues to be valid beyond the date of expiration in any hearing held under § 52.231 before operation begins under a combined license that references the design certification.

(c) An applicant for a construction permit or a combined license may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 52.121 Application for renewal.

(a) Not less than twelve nor more than thirty-six months before the expiration of the initial fifteen-year period, or any later renewal period, any person may apply for renewal of the certification. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application. The Commission will require, prior to renewal of certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if this information is necessary for the Commission to make its safety determination. Notice and comment procedures must be used for a rulemaking proceeding on the application for renewal. The Commission, in its discretion, may require the use of additional procedures in individual renewal proceedings.

(b) A design certification, either original or renewed, for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in certain proceedings, in accordance with the provisions of § 52.119.

(c) The Commission shall refer a copy of the application for renewal to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety and shall apply the criteria set forth in § 52.123.

§ 52.123 Criteria for renewal.

(a) The Commission shall issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Atomic Energy Act and the Commission's regulations applicable and in effect at the time the certification was issued. The Commission may impose other requirements after it determines that there is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements and that the direct and indirect costs of implementing those requirements are justified in view of this increased protection. In addition, the applicant for renewal may request an amendment to the design certification. The Commission shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act and the Commission's regulations in effect at the time of renewal. If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification must be filed in accordance with this subpart.

(b) Denial of renewal does not bar the applicant, or another applicant, from filing a new application for certification of the design, which proposes design changes that correct the deficiencies cited in the denial of the renewal.

§ 52.125 Duration of renewal.

Each renewal of certification for a standard design will be for not less than ten nor more than fifteen years.

§ 52.127 Finality of standard design certifications.

(a)(1)(i) Notwithstanding any provision in 10 CFR 50.109, while a standard design certification rule is in effect under § 52.119 or 52.125, the Commission may not modify, rescind,

or impose new requirements on the certification information, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that the change:

(A) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;

(B) Is necessary to provide adequate protection of the public health and safety or the common defense and security; or

(C) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security.

(ii) The rulemaking procedures must provide for notice and comment and an opportunity for the party which applied for the certification to request an informal hearing which uses the procedures described in § 52.113 of this subpart.

(2) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant by action taken under paragraphs (a)(3) or (b)(1) of this section.

(3) While a design certification rule is in effect under § 52.119 or 52.125, unless (i) a modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security, and (ii) special circumstances as defined in 10 CFR 50.12(a) are present, the Commission may not impose new requirements by plant-specific order on any part of the design of a specific plant referencing the design

certification rule if that part was approved in the design certification. In addition to the factors listed in 10 CFR 50.12(a), the Commission shall consider whether the special circumstances which 10 CFR 50.12(a)(2) requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.

(4) Except as provided in 10 CFR 2.758, in making the findings required for issuance of a combined license or operating license, or for any hearing under § 52.231, the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b)(1) An applicant or licensee who references a standard design certification rule may request an exemption from one or more elements of the design certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). In addition to the factors listed in § 50.12(a), the Commission shall consider whether the special circumstances which § 50.12(a)(2) requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. The granting of an exemption on request of an applicant must be subject to litigation in the same manner as other issues in the operating license or combined license hearing.

(2) Subject to § 50.59, a licensee who references a standard design certification rule may make changes to the design of the nuclear power facility, without prior Commission approval, unless the proposed change involves a change to the design as described in the rule certifying the design. The licensee shall maintain records of all changes to the facility and these records must be maintained and available for audit until the date of termination of the license.

(c) The Commission will require, prior to granting a construction permit, combined license, or operating license which references a standard design certification rule, that

information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if such information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

#### Subpart E - Standard Design Approvals

##### § 52.131 Scope of subpart.

This subpart sets out procedures for the filing, NRC staff review, and referral to the Advisory Committee on Reactor Safeguards of standard designs for a nuclear power reactor of the type described in § 50.22 of this chapter or major portions thereof.

##### § 52.133 Filing of applications.

(a) Any person may submit a proposed preliminary or final standard design for a nuclear power reactor of the type described in 10 CFR 50.22 to the NRC staff for its review. The submittal may consist of either the preliminary or final design for the entire reactor facility or the preliminary or final design of major portions thereof.

(b) The submittal for review of the standard design must be made in the same manner and in the same number of copies as provided in §§ 50.4 and 50.30 of this chapter for license applications.

(c) The fees associated with the filing and review of the application are set forth in 10 CFR Part 170.

§ 52.135 Contents of applications.

The submittal for review of the standard design must include the information described in §§ 50.33 (a) through (d) of this chapter and the applicable technical information required by § 50.34 of this chapter, as appropriate [other than that required by 10 CFR 50.34(a)(6) and (10), 50.34(b)(1), (6)(i), (ii), (iv), and (v) and 50.34(b)(7) and (8)], 10 CFR 50.34a, and 52.107(a)(1)(i) through (v), and (vii). The submittal must also include a description, analysis, and evaluation of the interfaces between the submitted design and the balance of the nuclear power plant. With respect to the requirements of § 50.34(a)(1) of this chapter, the submittal for review of a standard design must include the site parameters postulated for the design, and an analysis and evaluation of the design in terms of the postulated site parameters. The information submitted under § 50.34(a)(7) of this chapter, must be limited to the quality assurance program to be applied to the design, procurement, and fabrication of the structures, systems, and components for which design review has been requested. The information submitted under § 50.34(a)(9) of this chapter must be limited to the qualifications of the person submitting the standard design to design the reactor or major portion thereof. The submittal must also include information pertaining to design features that affect plans for coping with emergencies in the operation of the reactor or a major portion thereof.

§ 52.137 Referral to the ACRS.

Once the NRC staff has initiated a technical review of a submittal under this subpart, the submittal will be referred to the Advisory Committee on Reactor Safeguards (ACRS) for a review and report.

§ 52.139 Staff approval of design.

(a) Upon completion of their review of a submittal under this subpart, the NRC staff shall publish a determination in the *Federal Register* as to whether or not the preliminary or final

design is acceptable, subject to appropriate conditions, and make an analysis of the design in the form of a report available at the NRC Web site, <http://www.nrc.gov>.

(b) A standard design approval issued under this subpart is valid for five years from the date of issuance. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a construction permit or an operating license which references the design approval and is docketed before the date of expiration of the design approval.

§ 52.141 Finality of the design approval.

(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their review of any individual facility license application that incorporates by reference a design approved in accordance with this paragraph unless there exists significant new information that substantially affects the earlier determination or other good cause.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, and other presiding officers in any proceeding under Part 2 of this chapter.

§ 52.143 Information requests.

Information requests to the approval holder regarding an approved design must be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

Subpart F – [Reserved]

## Subpart G – Combined Licenses

### § 52.201 Scope of subpart.

This subpart sets out the requirements and procedures applicable to Commission issuance of combined licenses for nuclear power facilities.

### § 52.203 Relationship to other subparts.

(a) An application for a combined license under this subpart may, but need not, reference a standard design certification or standard design approval issued under Subparts D or E of this part, or an early site permit or site report issued under Subparts A or B of this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a design certification is qualified to supply such design, the Commission will entertain an application for a combined license that references a standard design certification issued under Subpart D of this part only if the entity that sponsored and obtained the certification supplies the certified design for the applicant's use.

(b) The Commission will require, prior to granting a combined license that references a standard design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if such information is necessary for the Commission to make its safety determinations, including the determination that the application is consistent with the certification information.

### § 52.205 Filing of applications.

(a) Any person except one excluded by 10 CFR 50.38 may file an application for a combined license for a nuclear power facility with the Director of Nuclear Reactor Regulation. The applicant shall comply with the filing requirements of 10 CFR 50.30 (a) and (b), as they would apply to an application for a nuclear power plant construction permit.

(b) The fees associated with the filing and review of the application are set forth in 10 CFR Part 170.

§ 52.207 Contents of applications; general information.

The application must contain all of the information required by 10 CFR 50.33, as that section would apply to applicants for construction permits and operating licenses, and 10 CFR 50.33a, as that section would apply to an applicant for a nuclear power plant construction permit. In particular, the applicant shall comply with the requirement of 10 CFR 50.33a(b) regarding the submission of antitrust information.

§ 52.209 Contents of applications; training and qualification of nuclear power plant personnel.

The application must describe the training program required by § 50.120 of this chapter. The training program described in the application must be established, implemented and maintained no later than eighteen (18) months prior to the scheduled date for initial loading of fuel, as provided for in § 52.231(a).

§ 52.211 Contents of applications; technical information.

*(a) Early site permit.*

(1) If the application references an early site permit, the application need not contain information or analyses submitted to the Commission in connection with the early site permit, but must contain, in addition to the information and analyses otherwise required:

(i) Information sufficient to demonstrate that the design of the facility falls within the site parameters specified in the early site permit;

(ii) Information necessary to resolve any other significant environmental issue with respect to the site not considered in any previous proceeding on the site or the design; and

(iii) A demonstration that all terms and conditions of the early site permit have been satisfied.

(2) If the application does not reference an early site permit, the applicant must comply with the requirements of 10 CFR 50.30(f) by including with the application an environmental report prepared in accordance with the provisions of Subpart A of 10 CFR Part 51.

(3) If the application does not reference an early site permit which contains a site redress plan as described in § 52.17(c), and if the applicant wishes to be able to perform the activities at the site allowed by 10 CFR 50.10(e)(1), then the application must contain the information required by § 52.17(c).

(b) The application must contain the technically relevant information required of applicants for an operating license by 10 CFR 50.34 in a final safety analysis report.

(1) If the application does not reference a certified design, the application must comply with the requirements of § 52.107(a)(2) for level of design information, and must contain the technical information required by §§ 52.107(a)(1) (i), (ii), (iv), and (3); § 52.107(b)(2); and, if the design is modular, § 52.107(b)(3).

(2) If the application does not reference a certified design, the application must contain a plant-specific probabilistic risk assessment (PRA).

(3) If a prototype plant is used to comply with the requirements of § 52.107(b)(2), then the NRC may impose additional licensing requirements on siting, safety features, or operational conditions for the prototype plant to protect the public, the plant staff, and the plant itself from the possible consequences of failures during the testing period.

(4) An application referencing a certified design must include in the final safety analysis report the information approved for incorporation by reference in a design certification rule;

describe those portions of the design that are not described in the certified design, such as the service water intake structure and the ultimate heat sink; demonstrate compliance with the interface requirements established for the design under § 52.107(a)(1); and have available for audit procurement specifications and construction and installation specifications in accordance with §§ 52.107(a)(2) and 52.203(b).

(5) An application referencing a certified design must include a plant-specific PRA that uses the design-specific PRA and is updated to account for site-specific design information and any design changes.

(c) The application must include the proposed inspections, tests and analyses, including those applicable to emergency planning, which the licensee shall perform and the acceptance criteria necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the combined license, the provisions of the Atomic Energy Act, and the NRC's regulations.

(1) If the application references a certified standard design, the inspections, tests, analyses, and acceptance criteria contained in the certified design must apply to those portions of the facility design that are covered by the design certification.

(2) The application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notification required by § 52.217 must indicate that the application includes this notification.

(d) The application must contain emergency plans that provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(1) If the application references an early site permit, the application may incorporate by reference emergency plans, or major features of emergency plans, approved in connection with the issuance of the permit. If the application incorporates by reference an emergency plan or major features of such a plan, the application must include information that updates and corrects the information previously provided under § 52.17(b), and discuss whether the new information materially changes [alters] the bases for compliance with the applicable requirements. New information that materially changes the bases for the Commission's determination on the matters in § 52.17(b) must be subject to litigation during the construction permit, duplicate design license, or combined license proceeding in the same manner as other issues material to those proceedings.

(2)(i) If the application does not reference an early site permit, or if no emergency plans were approved in connection with the issuance of the permit, the applicant shall make good faith efforts to obtain certifications from the local and State governmental agencies with emergency planning responsibilities that:

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii) The application must contain any certifications that have been obtained. If these certifications cannot be obtained, the application must contain information, including a utility plan, sufficient to show that the proposed plans nonetheless provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

§ 52.213 Standards for review of applications.

Applications filed under this subpart will be reviewed according to the standards set out in 10 CFR Parts 20, 50, 51, 55, 73, and 100 as they apply to applications for construction permits and operating licenses for nuclear power plants, and as those standards are technically relevant to the design proposed for the facility.

§ 52.215 Applicability of NRC requirements.

(a) An applicant shall comply with all requirements in 10 CFR Chapter I applicable to applicants for construction permits and limited work authorizations under 10 CFR 50.10.

(b) After a combined license is issued but before the Commission has authorized operation under § 52.231, the licensee shall comply with all requirements in title 10 of this chapter applicable to holders of construction permits for nuclear power reactors.

(c) After the Commission has authorized operation under § 52.231, the licensee shall comply with all requirements in 10 CFR Chapter I applicable to holders of operating licenses for nuclear power reactors. Any limitations contained in 10 CFR Part 50 regarding applicability of the provisions to certain classes of facilities continue to apply. Provisions of 10 CFR Part 50 that do not apply to holders of combined licenses issued under this subpart include §§ 50.55(a), (b) and (d), and 50.58(a).

§ 52.217 Administrative review of applications.

A proceeding on a combined license is subject to all applicable procedural requirements contained in 10 CFR Part 2, including the requirements for docketing (§ 2.101) and issuance of a notice of hearing (§ 2.104). If an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of

hearing. All hearings on combined licenses are governed by the procedures contained in 10 CFR Part 2.

§ 52.219 Referral to the ACRS.

The Commission shall refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application that concern safety and shall apply the criteria set forth in § 52.213, in accordance with the finality provisions of this part.

§ 52.221 Environmental review.

If the application references an early site permit and/or a design certification rule, the environmental review must focus on whether the design of the facility falls within the site parameters specified in the early site permit and any other significant environmental issue not considered in any previous proceeding on the site or the design. If the application does not reference an early site permit, the environmental review procedures set out in 10 CFR Part 51 with respect to a construction permit must be followed, including the issuance of a final environmental impact statement, but excluding the issuance of a supplement under 10 CFR 51.95(a).

§ 52.223 Authorization to conduct site activities.

(a)(1) If the application references an early site permit that contains a site redress plan as described in § 52.17(c) the applicant is authorized by § 52.25 to perform the site preparation activities described in 10 CFR 50.10(e)(1).

(2) If the application does not reference an early site permit which contains a redress plan, the applicant may not perform the site preparation activities allowed by 10 CFR 50.10(e)(1) without first submitting a site redress plan in accord with § 52.211(a)(3) and obtaining the

separate authorization required by 10 CFR 50.10(e)(1). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by 10 CFR 50.10(e)(2) and has determined that the site redress plan meets the criteria in § 52.17(c).

(3) Authorization to conduct the activities described in 10 CFR 50.10(e)(3)(i) may be granted only after the presiding officer in the combined license proceeding makes the additional finding required by 10 CFR 50.10(e)(3)(ii).

(b) If, after an applicant for a combined license has performed the activities permitted by paragraph (a) of this section, the application for the license is withdrawn or denied, and the early site permit referenced by the application expires, then the applicant shall redress the site in accord with the terms of the site redress plan. If a use not envisaged in the redress plan is found for the site or parts thereof before redress is complete, the applicant shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

#### § 52.225 Exemptions and variances.

(a) Applicants for a combined license under this subpart, or any amendment to a combined license, may include in the application a request, under 10 CFR 50.12, for an exemption from one or more of the Commission's regulations, including any part of a design certification rule. The Commission may grant such a request if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a) or 52.127(b)(1) if the exemption includes any part of the design certification rule.

(b) An applicant for a combined license, or any amendment to a combined license, who has filed an application referencing an early site permit issued under this subpart may include in the application a request for a variance from one or more elements of the permit. In determining whether to grant the variance, the Commission shall apply the same technically relevant criteria

as were applicable to the application for the original or renewed site permit. Issuance of the variance is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

§ 52.227 Issuance of combined licenses.

(a)(1) The Commission shall issue a combined license for a nuclear power facility upon finding that the applicable requirements of 10 CFR 50.40, 50.42, 50.43, 50.47, and 50.50 have been met, and that there is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's rules and regulations.

(2) The Commission may also find, at the time it issues the combined license, that certain acceptance criteria in one or more of the inspections, tests, analyses, and acceptance criteria (ITAAC) in the combined license have been met. Such a finding will preclude any required finding under § 52.231(g) with respect to that ITAAC.

(b)(1) The Commission shall identify within the combined license the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations.

(2) Any modification to, addition to, or deletion from the terms of a combined license, including any modification to, addition to, or deletion from the inspections, tests, analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on these amendments.

(3) The Commission may issue and make immediately effective any amendment to a combined license upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed in accordance with the procedures specified in 10 CFR 50.91.

(c) If the combined license does not reference a certified design, then a licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) under the applicable change processes in 10 CFR Part 50 (e.g., § 50.54, § 50.59, or § 50.90).

(d) If the combined license references a certified design, then --

(1) Changes to or departures from information within the scope of the referenced design certification rule are subject to the applicable change processes in that rule; and

(2) Changes that are not within the scope of the referenced design certification rule are subject to the applicable change processes in 10 CFR Part 50 unless they involve changes to or non-compliance with information within the scope of the referenced design certification rule, in which case the applicable provisions of this section and/or the design certification rule apply.

(e) A combined license is issued for a specified period not to exceed forty (40) years from the date of issuance.

§ 52.229 Inspection during construction.

(a) Holders of combined licenses shall comply with the provisions of 10 CFR 50.70 and 50.71.

(b) With respect to activities subject to an ITAAC, an applicant for a combined license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and pre-operational activities, even though the NRC may not have found that any particular ITAAC has been satisfied.

(c) The licensee shall notify the NRC that the inspections, tests, or analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

(d) In the event that an activity is subject to an ITAAC and the licensee has not demonstrated that the ITAAC has been satisfied, the licensee may take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with the applicable change process in the referenced design certification rule, or request a license amendment under § 52.227(b), as applicable.

(e) The NRC staff shall ensure that the required inspections, tests, or analyses in the ITAAC are performed. At appropriate intervals during construction, the NRC shall publish notices in the *Federal Register* of the licensee's notification that inspections, tests, or analyses have been completed and acceptance criteria have been met.

§ 52.231 Operation under a combined license.

(a) Not less than one hundred and eighty days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a combined license under Subpart G of this part, the Commission shall publish notice of intended operation in the *Federal Register*. That document must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance

criteria of the ITAAC in the combined license, except for those ITAAC that the Commission found were met under § 52.227(a)(2).

(b) A request for hearing under paragraph (a) of this section must show, prima facie, that --

(1) One or more of the acceptance criteria of the ITAAC in the combined license have not been, or will not be met; and

(2) The specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(c) After receiving a request for a hearing, the Commission expeditiously shall either deny or grant the request. If the request is granted, the Commission shall determine, after considering petitioners' prima facie showing and any answers thereto, whether during a period of interim operation, there will be reasonable assurance of adequate protection of the public health and safety. If the Commission determines that there is such reasonable assurance, it shall allow operation during an interim period under the combined license.

(d) The Commission, in its discretion, shall determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and shall state its reasons therefor.

(e) The Commission shall, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the combined license will be processed as a request for action in accord with 10 CFR 2.206. The petitioner shall file the

petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the Commission shall determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the combined license will not be affected by the granting of the petition unless the order is made immediately effective.

(g) Prior to operation of the facility, the Commission shall find that the acceptance criteria of the ITAAC in the combined license are met, except for those ITAAC that the Commission found were met under § 52.227(a)(2). If the combined license is for a modular design, each reactor module may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the design certification rule or combined license, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a hearing under paragraph (a) of this section, their expiration will occur upon final Commission action in such proceeding. However, subsequent changes to the facility or procedures described in the final safety analysis report (as updated) must comply with the requirements in § 52.227(c) or (d), as applicable.

#### Subpart H – Manufacturing Licenses

##### § 52.241 Scope of subpart.

(a) Section 101 of the Atomic Energy Act of 1954, as amended, and § 50.10 of this chapter require a Commission license to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import or export any production or utilization facility. The regulations in 10 CFR Part 50 require the issuance of a construction permit by the Commission before commencement of construction of a production or utilization facility, and the issuance of an operating license before operation of the facility. The provisions

of 10 CFR Part 50 relating to the facility licensing process are, in general, predicated on the assumption that the facility will be assembled and constructed on the site at which it is to be operated. In those circumstances, both facility design and site-related issues can be considered in the initial, construction permit stage of the licensing process.

(b) Under the Atomic Energy Act, a license may be sought and issued authorizing the manufacture of facilities but not their construction and installation at the sites on which the facilities are to be operated. Prior to the “commencement and construction,” as defined in § 50.10(c) of this chapter, of a facility (manufactured under such a Commission license) on the site at which it is to operate—that is preparation of the site and installation of the facility—a construction permit, combined license, or duplicate plant license that, among other things, reflects approval of the site on which the facility is to be operated, must be issued by the Commission. This subpart sets out the particular requirements and provisions applicable to situations where nuclear power reactors to be manufactured under a Commission license and subsequently installed at the site under a Commission construction permit, combined license, or duplicate plant license, are of the type described in § 50.22 of this chapter.

§ 52.243 Relationship to other subparts.

(a) *Referencing a manufacturing license.* An application for a construction permit, operating license or combined license to construct a nuclear power plant which is to be manufactured under a manufacturing license issued under this subpart need not contain the information or analyses that have been previously approved by the Commission in connection with the issuance of the manufacturing license. The application must reference the manufacturing license, and provide sufficient information to demonstrate that the site on which the reactor(s) is to be located and operated fits within the postulated site parameters specified in the manufacturing license.

(b) *Amendment of manufacturing license to reflect final reactor design.* The holder of a manufacturing license issued under this subpart shall submit to the Commission the final design of the nuclear power reactor(s) covered by the license as soon as such design has been completed. The submittal must be in the form of an application for amendment of the manufacturing license.

(c) *Application for construction permit or combined license referencing a manufacturing license.* An application for a permit to construct a nuclear power reactor(s) or a combined license that is the subject of an application for a manufacturing license pursuant to this subpart need not contain information or analyses that have previously been submitted to the Commission in connection with the application for a manufacturing license. However, the application must comply with §§ 50.34(a) and 50.34a of this chapter, and provide sufficient information to demonstrate that the site on which the reactor(s) is to be operated falls within the postulated site parameters specified in the relevant manufacturing license application.

(d) *Approval of construction permit or combined license referencing a manufacturing license.* The Commission may issue a permit to construct a nuclear power reactor(s) or a combined license that is the subject of an application for a manufacturing license pursuant to this subpart if the

Commission- -

(1) Finds that the site on which the reactor is to be operated falls within the postulated site parameters specified in the relevant application for a manufacturing license; and

(2) Makes the findings otherwise required by 10 CFR Part 50. A construction permit or combined license may not be issued until the relevant manufacturing license has been issued.

(e) *Approval of operating license referencing a manufacturing license.* An operating license for a nuclear power reactor(s) that has been manufactured under a Commission license issued under this subpart may be issued by the Commission under 10 CFR 50.57 and Subpart A of Part 51 of this chapter except that the Commission shall find, under 10 CFR 50.57(a)(1), that construction of the reactor(s) has been substantially completed in conformity with both the manufacturing license and the construction permit and the applications therefor, as amended, and the provisions of the Act, and the rules and regulations of the Commission. Notwithstanding the other provisions of this paragraph, no application for an operating license for a nuclear power reactor(s) that has been manufactured under a Commission license issued under this subpart will be docketed until the application for an amendment to the relevant manufacturing license required by § 52.249 has been docketed.

(f) *Prohibition against transport of nuclear power reactor manufactured under this subpart.* The prohibition in § 50.10(c) of this chapter against commencement of construction of a production or utilization facility prior to issuance of a construction permit applies to the transport of a nuclear power reactor(s) manufactured pursuant to this subpart from the manufacturing facility to the site at which the reactor(s) will be installed and operated. In addition, such nuclear power reactor(s) may not be removed from the manufacturing site until the final design of the reactor(s) has been approved by the Commission in accordance with § 52.249.

§ 52.245 Filing and contents of applications.

(a) An application for a manufacturing license under this subpart must be submitted, as specified in § 50.4 of this chapter and meet all the requirements of §§ 50.34(a)(1)-(9) and 50.34a(a) and (b) of this chapter except that the preliminary safety analysis report must be designated as a “design report” and any required information or analyses relating to site matters must be predicated on postulated site parameters which must be specified in the application.

The application must also include information pertaining to design features of the proposed reactor(s) that affect plans for coping with emergencies in the operation of the reactor(s).

(b) An applicant for a manufacturing license under this subpart shall submit with the application an environmental report as required of applicants for construction permits in accordance with Subpart A of Part 51 of this chapter. However, the report must be directed at the manufacture of the reactor(s) at the manufacturing site; and, in general terms, at the construction and operation of the reactor(s) at a hypothetical site or sites having characteristics that fall within the postulated site parameters. The related draft and final environmental impact statement prepared by the NRC staff will be similarly directed.

(c) The financial information submitted under § 50.33(f) of this chapter and Appendix C of Part 50 must be directed at a demonstration of the financial qualifications of the applicant for the manufacturing license to carry out the manufacturing activity for which the license is sought.

(d) The fees associated with the filing and review of the application are set forth in 10 CFR Part 170.

§ 52.247 Standards for review of application.

Applications filed under this subpart will be reviewed for compliance with the standards set out in 10 CFR Part 20, Part 50 and its appendices, and parts 73 and 100 as they apply to applications for construction permits and operating licenses for nuclear power plants, except as otherwise specified in this subpart or as the context otherwise indicates. The requirement in § 50.58 of this chapter for review of the application by the Advisory Committee on Reactor Safeguards and the holding of a public hearing, apply in context, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, to licenses under this subpart to manufacture nuclear power reactors (manufacturing licenses) to be operated at sites not identified in the license application.

§ 52.249 Applicability of NRC requirements

An applicant shall comply with all requirements in title 10 of this chapter applicable to applicants for construction permits and operating licenses under title 10 of this chapter, except §§ 50.10(b) and (c), 50.12(b), 50.23, 50.30(d), 50.34(a)(10), 50.34a(c), 50.35(a) and (c), 50.40(a), 50.45, 50.55(d), 50.56 of this chapter and Appendix J of 10 CFR Part 50 do not apply to manufacturing licenses. Appendices E and H of 10 CFR Part 50 apply to manufacturing licenses only to the extent that the requirements of these appendices involve facility design features.

§ 52.251 Referral to the ACRS.

The Commission shall refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety.

§ 52.253 Issuance of manufacturing license.

(a) The Commission may issue a license to manufacture one or more nuclear power reactors to be operated at sites not identified in the license application if the Commission finds that:

(1) The applicant has described the proposed design of and the site parameters postulated for the reactor(s), including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features of components incorporated therein for the protection of the health and safety of the public.

(2) Further technical or design information that may be required to complete the design report and which can reasonably be left for later consideration, will be supplied in a supplement to the design report.

(3) Safety features or components, if any, that require research and development has been described by the applicant and the applicant has identified, and there will be conducted a research and development program reasonably designed to resolve any safety questions associated with the features of components; and

(4) On the basis of the foregoing, there is reasonable assurance that:

(i) Such safety questions will be satisfactorily resolved before any of the proposed nuclear power reactor(s) are removed from the manufacturing site; and

(ii) Taking into consideration the site criteria contained in Part 100 of this chapter, the proposed reactor(s) can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design of the reactor(s) without undue risk to the health and safety of the public.

(5) The applicant is technically and financially qualified to design and manufacture the proposed nuclear power reactor(s).

(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public.

(7) On the basis of the evaluations and analyses of the environmental effects of the proposed action required by Subpart A of Part 51 of this chapter and § 52.247, the action called for is the issuance of the license.

(b) When an applicant has supplied initially all of the technical information required to complete the application, including the final design of the reactor(s), the findings required for the issuance of the license will be appropriately modified to reflect that fact.

(c) Each manufacturing license issued under this subpart will specify the number of nuclear power reactors authorized to be manufactured and the latest date of the completion of

the manufacture of all such reactors. Upon good cause shown, the Commission will extend the completion date for a reasonable period of time.

§ 52.255 Duration of design approval.

A nuclear plant design that is approved as part of the issuance of a manufacturing license is valid for five years from the date of issuance of the manufacturing license.

§ 52.257 Finality of the manufacturing license.

In making the findings required by this part for the issuance of a construction permit or an operating license for a nuclear power reactor(s) that has been manufactured under a Commission license issued under this subpart, or an amendment to such a manufacturing license, construction permit, or operating license, the Commission will treat as resolved those matters which have been resolved at an earlier stage of the licensing process, unless there exists significant new information that substantially affects the conclusion(s) reached at the earlier stage or other good cause.

Subpart I - Duplicate Design Licenses

§ 52.261 Scope of subpart.

(a) Section 101 of the Atomic Energy Act of 1954, as amended, and § 50.10 of this chapter require a Commission license to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import or export any production or utilization facility. The regulations in 10 CFR Part 50 require the issuance of a construction permit by the Commission before commencement of construction of a production or utilization facility, except as provided in § 50.10(e) of this chapter, and the issuance of an operating license before the operation of the facility.

(b) The Commission's regulations in 10 CFR Part 2 specifically provide for the holding of hearings on particular issues separately from other issues involved in hearings in licensing proceedings (10 CFR 2.761a and 10 CFR Part 2 Appendix A, Section I(c)), and for the consolidation of adjudicatory proceedings and of the presentations of parties in adjudicatory proceedings such as licensing proceedings (10 CFR 2.715a and 2.716).

(c) This subpart sets out the particular requirements and provisions applicable to situations in which applications are filed by one or more applicants for licenses to construct and operate nuclear power reactors of essentially the same design to be located at different sites.

(d) If the design for the power reactor(s) proposed in a particular application is not identical to the others, that application may not be processed under this subpart and Subpart D of Part 2 of this chapter.

#### § 52.263 Relationship to other subparts.

Except as otherwise specified in this subpart or as the context otherwise indicates, the provisions of 10 CFR Part 50, applicable to construction permits and operating licenses, including the requirement in § 50.58 of this chapter for review of the application by the Advisory Committee on Reactor Safeguards and the holding of public hearings, apply to construction permits and operating license subject to this subpart.

#### § 52.265 Filing and contents of applications.

(a) Applications for construction permits submitted under this subpart must include the information required by §§ 50.33, 50.33a, 50.34(a) and 50.34a (a) and (b) of this chapter, and be submitted as specified in § 50.4 of this chapter. The applicant shall also submit the information required by § 51.50 of this chapter.

(b) For the technical information required by §§ 50.34(a)(1) through (5) and (8) and 50.34a (a) and (b) of this chapter, reference may be made to a single preliminary safety analysis of the design<sup>1</sup> which, for the purposes of 10 CFR 50.34(a)(1) includes one set of site parameters postulated for the design of the reactors, and an analysis and evaluation of the reactors in terms of such postulated site parameters. This single preliminary safety analysis must also include information pertaining to design features of the proposed reactors that affect plans for coping with emergencies in the operation of the reactors, and must describe the quality assurance program with respect to aspects of design, fabrication, procurement and construction that are common to all of the reactors.

(c) Applications for operating licenses submitted pursuant to this subpart must include the information required by §§ 50.33, 50.34 (b) and (c), and 50.34a(c) of this chapter. The applicant shall also submit the information required by § 51.53 of this chapter. For the technical information required by §§ 50.34(b)(2) through (5) and 50.34a(c), reference may be made to a single final safety analysis of the design.

(d) The fees associated with the filing and review of the application are set forth in 10 CFR Part 170.

Subpart J – [Reserved]

Subpart K – [Reserved]

Subpart L – [Reserved]

Subpart M – Enforcement

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<sup>1</sup> As used in this subpart, the design of a nuclear power reactor included in a single referenced safety analysis report means the design of those structures, systems, and components important to radiological health and safety and the common defense and security.

§ 52.401 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of --

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974, as amended; or
- (3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

- (1) For violations of --
  - (i) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;
  - (ii) Section 206 of the Energy Reorganization Act;
  - (iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;
  - (iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.
- (2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 52.403 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under Sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the

regulations in Part 52 are issued under one or more of sections 161b, 161i, or 160o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in Part 52 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 52.1, 52.3, 52.5, 52.8, 52.11, 52.13, 52.15, 52.17, 52.18, 52.19, 52.21, 52.23, 52.24, 52.27, 52.29, 52.31, 52.33, 52.37, 52.39, 52.101, 52.103, 52.105, 52.107, 52.109, 52.111, 52.113, 52.115, 52.117, 52.119, 52.121, 52.123, 52.125, 52.201, 52.203, 52.205, 52.207, 52.209, 52.211, 52.213, 52.215, 52.217, 52.219, 52.221, 52.225, 52.227, 52.231, 52.401, 52.403.

## Appendix A - Design Certification Rule for the U.S. Advanced Boiling Water Reactor

### *I. Introduction*

Appendix A constitutes the standard design certification for the U.S. Advanced Boiling Water Reactor (ABWR) design, in accordance with 10 CFR Part 52, Subpart B. The applicant for certification of the U.S. ABWR design was GE Nuclear Energy.

### *II. Definitions*

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information.

Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

E. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (hereinafter Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.107, with the exception of generic technical specifications and conceptual design information;
2. Information required for a final safety analysis report under 10 CFR 50.34;
3. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and

4. Combined license (COL) action items (COL license information), which identify certain matters that shall be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. Tier 2\* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2\* information under Section VIII.B.6.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means: (i) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or (ii) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2, 10 CFR 52.3, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

### *III. Scope and Contents*

A. Tier 1, Tier 2, and the generic technical specifications in the U.S. ABWR Design Control Document, GE Nuclear Energy, Revision 4 dated March 1997, are approved for incorporation by reference by the Director of the Office of the *Federal Register* in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the generic DCD may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is

available for examination and copying at the NRC Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20582 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2, and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information, as set forth in the generic DCD, and the "Technical Support Document for the ABWR" are not part of this appendix. Tier 2 references to the probabilistic risk assessment (PRA) in the ABWR Standard Safety Analysis Report do not incorporate the PRA into Tier 2.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the U.S. ABWR design or NUREG-1503, "Final Safety Evaluation Report related to the Certification of the Advanced Boiling Water Reactor Design," (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site-specific design parameters, provided the design activities do not affect the DCD or conflict with the interface requirements.

#### *IV. Additional Requirements and Restrictions*

A. An applicant for a license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.207, 52.209, and 52.211, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;
2. Include, as part of its application:
  - a. A plant-specific DCD containing the same information and utilizing the same organization and numbering as the generic DCD for the U.S. ABWR design, as modified and supplemented by the applicant's exemptions and departures;
  - b. The reports on departures from and updates to the plant-specific DCD required by Section X.B of this appendix;
  - c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;
  - d. Information demonstrating compliance with the site parameters and interface requirements;
  - e. Information that addresses the COL action items; and
  - f. Information required by 10 CFR 52.107(a) that is not within the scope of this appendix.
3. Physically include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the U.S. ABWR DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR Part 50.

#### *V. Applicable Regulations*

A. Except as indicated in Paragraph B of this section, the regulations that apply to the U.S. ABWR design are in 10 CFR Parts 20, 50, 73, and 100, codified as of May 2, 1997, that are applicable and technically relevant, as described in the FSER (NUREG-1503) and Supplement No. 1.

B. The U.S. ABWR design is exempt from portions of the following regulations:

1. Paragraph (f)(2)(iv) of 10 CFR 50.34—Separate Plant Safety Parameter Display Console;
2. Paragraph (f)(2)(viii) of 10 CFR 50.34—Post-Accident Sampling for Boron, Chloride, and Dissolved Gases; and
3. Paragraph (f)(3)(iv) of 10 CFR 50.34—Dedicated Containment Penetration.

#### *VI. Issue Resolution*

A. The Commission has determined that the structures, systems, components, and design features of the U.S. ABWR design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the U.S. ABWR design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.127(a)(4) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held pursuant to 10 CFR 52.231, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements), and the rulemaking record for certification of the U.S. ABWR design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the U.S. ABWR design;

3. All generic changes to the DCD pursuant to and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD pursuant to and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in Section VIII.B.5.f of this appendix, all departures from Tier 2 pursuant to and in compliance with the change processes in Section VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC's final environmental assessment for the U.S. ABWR design and Revision 1 of the Technical Support Document for the U.S. ABWR, dated December

1994, for plants referencing this appendix whose site parameters are within those specified in the Technical Support Document.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.127(a)(4). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the DCD for the U.S. ABWR design, in order to request or participate in the hearing required by 10 CFR 52.217 or the hearing provided under 10 CFR 52.231, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from GE Nuclear Energy. The request must state with particularity:

- a. The nature of the proprietary or other information sought;

b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;

c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.217 or 10 CFR 52.231. If GE Nuclear Energy declines to provide the information sought, GE Nuclear Energy shall send a written response within ten (10) days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to GE Nuclear Energy), and GE Nuclear Energy's response. The Commission and presiding officer may order GE Nuclear Energy to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

#### *VII. Duration of This Appendix*

This appendix may be referenced for a period of 15 years from June 11, 1997, except as provided for in 10 CFR 52.119(b) and 52.121(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

### *VIII. Processes for Changes and Departures*

#### A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.127(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.127(a)(3).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.127(b)(1) and § 52.227(b). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

#### B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.127(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.119 or 52.125, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this

appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 50.12(a) are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2\* information, or the technical specifications, or requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is more than a minimal increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is more than a minimal increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.231(a), who believes that an applicant or licensee who references this appendix has not complied with Section VIII.B.5 of this appendix when departing from Tier 2 information, may petition the NRC to admit into the proceeding such a contention. In addition in compliance with the general requirements of 10 CFR 2.714(b)(2), the petition must demonstrate that the departure does not comply with Section VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.231 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with Section VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2\* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.127(a)(4).

b. A licensee who references this appendix may not depart from the following Tier 2\* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Fuel burnup limit (4.2).
- (2) Fuel design evaluation (4.2.3).
- (3) Fuel licensing acceptance criteria (Appendix 4B).

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.231(g), depart from the following Tier 2\* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2\* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) ASME Boiler & Pressure Vessel Code, Section III.
- (2) ACI 349 and ANSI/AISC N-690.
- (3) Motor-operated valves.
- (4) Equipment seismic qualification methods.
- (5) Piping design acceptance criteria.
- (6) Fuel system and assembly design (4.2), except burnup limit.
- (7) Nuclear design (4.3).
- (8) Equilibrium cycle and control rod patterns (App. 4A).
- (9) Control rod licensing acceptance criteria (App. 4C).
- (10) Instrument setpoint methodology.
- (11) EMS performance specifications and architecture.

(12) SSLC hardware and software qualification.

(13) Self-test system design testing features and commitments.

(14) Human factors engineering design and implementation process.

d. Departures from Tier 2\* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic technical specifications and other operational requirements are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.758(b) are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.231(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. The petition must comply with the general requirements of 10 CFR 2.714(b)(2) and must demonstrate why special circumstances as defined in 10 CFR 2.758(b) are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

*IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)*

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been satisfied.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been satisfied, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.227(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.227(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.231(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.231(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.231(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.227 and Section VIII of this appendix.

#### *X. Records and Reporting*

##### A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1 and Tier 2. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made pursuant to Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

##### B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any departures from the plant-specific DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 50.4.

2. An applicant or licensee who references this appendix shall submit updates to its plant-specific DCD, which reflect the generic changes to the generic DCD and the plant-specific departures made pursuant to Section VIII of this appendix. These updates must be filed in accordance with the filing requirements applicable to final safety analysis report updates in 10 CFR 50.4 and 50.71(e).

3. The reports and updates required by paragraphs B.1 and B.2 of this section must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the plant-specific DCD.

b. During the interval from the date of application to the date of issuance of a license, the report and any updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. During the interval from the date of issuance of a license to the date the Commission makes its findings under 10 CFR 52.231(g), the report must be submitted quarterly. Updates to the plant-specific DCD must be submitted annually.

d. After the Commission has made its finding under 10 CFR 52.231(g), reports and updates to the plant-specific DCD may be submitted annually or along with updates to the site-specific portion of the final safety analysis report for the facility at the intervals required by 10 CFR 50.71(e), or at shorter intervals as specified in the license.

## Appendix B - Design Certification Rule for the System 80+ Design

### *I. Introduction*

Appendix B constitutes design certification for the System 80+<sup>2</sup> standard plant design, in accordance with 10 CFR Part 52, Subpart B. The applicant for certification of the System 80+ design was Combustion Engineering, Inc. (ABB-CE), which is now Westinghouse Electric Company LLC.

### *II. Definitions*

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;

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<sup>2</sup> "System 80+" is a trademark of Westinghouse Electric Company LLC.

2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

E. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (hereinafter Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.107, with the exception of generic technical specifications and conceptual design information;
2. Information required for a final safety analysis report under 10 CFR 50.34;
3. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
4. Combined license (COL) action items (COL license information), which identify certain matters that shall be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified

in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. Tier 2\* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2\* information under Section VIII.B.6 of this appendix.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

(1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2, 10 CFR 52.3, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

### *III. Scope and Contents*

A. Tier 1, Tier 2, and the generic technical specifications in the System 80+ Design Control Document, ABB-CE, with revisions dated January 1997, are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the generic DCD may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for examination and copying at the NRC Public Document Room located at One White Flint North 11555 Rockville Pike (first floor) Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville

Pike, Rockville, Maryland 20582 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2, and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information, as set forth in the generic DCD, and the Technical Support Document for the System 80+ design are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the System 80+ design or NUREG-1462, "Final Safety Evaluation Report related to the Certification of the System 80+ Design," (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site-specific design parameters, provided the design activities do not affect the DCD or conflict with the interface requirements.

#### *IV. Additional Requirements and Restrictions*

A. An applicant for a license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.207, 52.209, and 52.211, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;
2. Include, as part of its application:

a. A plant-specific DCD containing the same information and utilizing the same organization and numbering as the generic DCD for the System 80+ design, as modified and supplemented by the applicant's exemptions and departures;

b. The reports on departures from and updates to the plant-specific DCD required by Section X.B of this appendix;

c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;

d. Information demonstrating compliance with the site parameters and interface requirements;

e. Information that addresses the COL action items; and

f. Information required by 10 CFR 52.107(a) that is not within the scope of this appendix.

3. Physically include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the System 80+ DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR Part 50.

#### *V. Applicable Regulations*

A. Except as indicated in paragraph B of this section, the regulations that apply to the System 80+ design are in 10 CFR Parts 20, 50, 73, and 100, codified as of May 9, 1997, that are applicable and technically relevant, as described in the FSER (NUREG-1462) and Supplement No. 1.

B. The System 80+ design is exempt from portions of the following regulations:

1. Paragraph (f)(2)(iv) of 10 CFR 50.34--Separate Plant Safety Parameter Display Console;
2. Paragraphs (f)(2) (vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34--Accident Source Terms;
3. Paragraph (f)(2)(viii) of 10 CFR 50.34--Post-Accident Sampling for Hydrogen, Boron, Chloride, and Dissolved Gases;
4. Paragraph (f)(3)(iv) of 10 CFR 50.34--Dedicated Containment Penetration; and
5. Paragraphs III.A.1(a) and III.C.3(b) of Appendix J to 10 CFR 50--Containment Leakage Testing.

#### *VI. Issue Resolution*

A. The Commission has determined that the structures, systems, components, and design features of the System 80+ design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the System 80+ design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.127(a)(4) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held pursuant to 10 CFR 52.231, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1,

Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements), and the rulemaking record for certification of the System 80+ design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the System 80+ design;

3. All generic changes to the DCD pursuant to and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD pursuant to and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in Section VIII.B.5.f of this appendix, all departures from Tier 2 pursuant to and in compliance with the change processes in Section VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC's final environmental assessment for the System 80+ design and the Technical Support Document for the System 80+ design, dated January 1995, for plants referencing this appendix whose site parameters are within those specified in the Technical Support Document.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.127(a)(4). The Commission reserves the right to require operational requirements for an

applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the DCD for the System 80+ design, in order to request or participate in the hearing required by 10 CFR 52.217 or the hearing provided under 10 CFR 52.231, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse. The request must state with particularity:

- a. The nature of the proprietary or other information sought;
- b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;
- c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.217 or 10 CFR 52.231. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within ten (10) days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

#### *VII. Duration of This Appendix*

This appendix may be referenced for a period of 15 years from June 11, 1997 except as provided for in 10 CFR 52.119(b) and 52.121(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

### *VIII. Processes for Changes and Departures*

#### A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.127(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.127(a)(3).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.127(b)(1) and § 52.227(b). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

#### B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.127(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.119 or 52.125, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this

appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 50.12(a) are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2\* information, or the technical specifications, or requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would - -

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if - -

(1) There is more than a minimal increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is more than a minimal increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.231(a), who believes that an applicant or licensee who references this appendix has not complied with Section VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.714(b)(2), the petition must demonstrate that the departure does not comply with Section VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.231 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with Section VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2\* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.127(a)(4).

b. A licensee who references this appendix may not depart from the following Tier 2\* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Maximum fuel rod average burnup.
- (2) Control room human factors engineering.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.231(g), depart from the following Tier 2\* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2\* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) ASME Boiler & Pressure Vessel Code, Section III.
- (2) ACI 349 and ANSI/AISC N-690.
- (3) Motor-operated valves.
- (4) Equipment seismic qualification methods.
- (5) Piping design acceptance criteria.
- (6) Fuel and control rod design, except burnup limit.
- (7) Instrumentation & controls setpoint methodology.
- (8) Instrumentation & controls hardware and software changes.
- (9) Instrumentation & controls environmental qualification.
- (10) Seismic design criteria for non-seismic category I structures.

d. Departures from Tier 2\* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic technical specifications and other operational requirements are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.758(b) are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.231(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such petition must comply with the general requirements of 10 CFR 2.714(b)(2) and must demonstrate why special circumstances as defined in 10 CFR 2.758(b) are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

#### *IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)*

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been satisfied.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been satisfied, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.227(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.227(b). Such rulemaking changes to the ITAAC must meet the requirements of Section VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.231(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.231(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.231(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.227 and Section VIII of this appendix.

## *X. Records and Reporting*

### A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1 and Tier 2. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made pursuant to Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

### B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any departures from the plant-specific DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 50.4.

2. An applicant or licensee who references this appendix shall submit updates to its plant-specific DCD, which reflect the generic changes to the generic DCD and the plant-specific departures made pursuant to Section VIII of this appendix. These updates must be filed in

accordance with the filing requirements applicable to final safety analysis report updates in 10 CFR 50.4 and 50.71(e).

3. The reports and updates required by paragraphs B.1 and B.2 of this section must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the plant-specific DCD.

b. During the interval from the date of application to the date of issuance of a license, the report and any updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. During the interval from the date of issuance of a license to the date the Commission makes its findings under 10 CFR 52.231(g), the report must be submitted quarterly. Updates to the plant-specific DCD must be submitted annually.

d. After the Commission has made its finding under 10 CFR 52.231(g), reports and updates to the plant-specific DCD may be submitted annually or along with updates to the site-specific portion of the final safety analysis report for the facility at the intervals required by 10 CFR 50.71(e), or at shorter intervals as specified in the license.

## Appendix C - Design Certification Rule for the AP600 Design

### *I. Introduction*

Appendix C constitutes the standard design certification for the AP600<sup>1</sup> design, in accordance with 10 CFR Part 52, Subpart B. The applicant for certification of the AP600 design is Westinghouse Electric Company LLC.

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<sup>1</sup>AP600 is a trademark of Westinghouse Electric Company LLC.

## *II. Definitions*

A. Generic design control document (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. Generic technical specifications means the information, required by 10 CFR 50.36 and 50.36a, for the portion of the plant that is within the scope of this appendix.

C. Plant-specific DCD means the document, maintained by an applicant or licensee who references this appendix, consisting of the information in the generic DCD, as modified and supplemented by the plant-specific departures and exemptions made under Section VIII of this appendix.

D. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (hereinafter Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

E. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (hereinafter Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a

sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in Section III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.107, with the exception of generic technical specifications and conceptual design information;
2. Information required for a final safety analysis report under 10 CFR 50.34;
3. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
4. Combined license (COL) action items (combined license information), which identify certain matters that must be addressed in the site-specific portion of the final safety analysis report (FSAR) by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

5. The investment protection short-term availability controls in Section 16.3 of the DCD.

F. Tier 2\* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of this appendix. This designation expires for some Tier 2\* information under Section VIII.B.6.

G. Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses means:

(1) Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

(2) Changing from a method described in the plant-specific DCD to another method unless that method has been approved by NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2, 10 CFR 52.3, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

### *III. Scope and Contents*

A. Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3), and the generic technical specifications in the AP600 DCD (12/99 revision) are approved for incorporation by reference by the Director of the Office of the Federal Register on January 24, 2000, in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the generic DCD may be obtained from Mr. Michael Corletti, Westinghouse Electric Company, P.O. Box 355, Pittsburgh, PA 15230-0355. A copy of the generic DCD is available for examination and copying at the NRC Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Copies are also available for examination at the NRC Library located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20582; and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3), and the generic technical specifications except as otherwise provided in this appendix. Conceptual design information in the generic DCD and the evaluation of severe

accident mitigation design alternatives in Appendix 1B of the generic DCD are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the AP600 design or NUREG-1512, "Final Safety Evaluation Report Related to Certification of the AP600 Standard Design," (FSER), then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site-specific design parameters, provided the design activities do not affect the DCD or conflict with the interface requirements.

#### *IV. Additional Requirements and Restrictions*

A. An applicant for a license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.207, 52.209, and 52.211, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix;
2. Include, as part of its application:
  - a. A plant-specific DCD containing the same information and utilizing the same organization and numbering as the generic DCD for the AP600 design, as modified and supplemented by the applicant's exemptions and departures;
  - b. The reports on departures from and updates to the plant-specific DCD required by Section X.B of this appendix;
  - c. Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;

d. Information demonstrating compliance with the site parameters and interface requirements;

e. Information that addresses the COL action items; and

f. Information required by 10 CFR 52.107(a) that is not within the scope of this appendix.

3. Physically include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the AP600 DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR Part 50.

#### *V. Applicable Regulations*

A. Except as indicated in paragraph B of this section, the regulations that apply to the AP600 design are in 10 CFR Parts 20, 50, 73, and 100, codified as of December 16, 1999, that are applicable and technically relevant, as described in the FSER (NUREG-1512) and the supplementary information for this section.

B. The AP600 design is exempt from portions of the following regulations:

1. Paragraph (a)(1) of 10 CFR 50.34--whole body dose criterion;
2. Paragraph (f)(2)(iv) of 10 CFR 50.34--Plant Safety Parameter Display Console;
3. Paragraphs (f)(2)(vii), (viii), (xxvi), and (xxviii) of 10 CFR 50.34--Accident Source Term in TID 14844;
4. Paragraph (a)(2) of 10 CFR 50.55a--ASME Boiler and Pressure Vessel Code;
5. Paragraph (c)(1) of 10 CFR 50.62--Auxiliary (or emergency) feedwater system;

6. Appendix A to 10 CFR Part 50, GDC 17--Offsite Power Sources; and
7. Appendix A to 10 CFR Part 50, GDC 19--whole body dose criterion.

#### *VI. Issue Resolution*

A. The Commission has determined that the structures, systems, components, and design features of the AP600 design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the AP600 design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.127(a)(4) in subsequent proceedings for issuance of a combined license, amendment of a combined license, or renewal of a combined license, proceedings held pursuant to 10 CFR 52.231, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic technical specifications and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information which the context indicates is intended as requirements), and the rulemaking record for certification of the AP600 design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the AP600 design;

3. All generic changes to the DCD pursuant to and in compliance with the change processes in Sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD pursuant to and in compliance with the change processes in Sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in Section VIII.B.5.f of this appendix, all departures from Tier 2 pursuant to and in compliance with the change processes in Section VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning severe accident mitigation design alternatives (SAMDA) associated with the information in the NRC's environmental assessment for the AP600 design and Appendix 1B of the generic DCD, for plants referencing this appendix whose site parameters are within those specified in the SAMDA evaluation.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.127(a)(4). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except in accordance with the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;

2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or

3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the AP600 DCD, in order to request or participate in the hearing required by 10 CFR 52.217 or the hearing provided under 10 CFR 52.231, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse. The request must state with particularity:

- a. The nature of the proprietary or other information sought;
- b. The reason why the information currently available to the public at the NRC Web site, <http://www.nrc.gov>, and/or at the NRC Public Document Room, is insufficient;
- c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and
- d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the *Federal Register* of the notice required either by 10 CFR 52.217 or 10 CFR 52.231. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within ten (10) days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request

(and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

#### *VII. Duration of This Appendix*

This appendix may be referenced for a period of 15 years from January 24, 2000, except as provided for in 10 CFR 52.119(b) and 52.121(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

#### *VIII. Processes for Changes and Departures*

##### A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.127(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.127(a)(3).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.127(b)(1) and § 52.227(b). The Commission will deny a request for an exemption from

Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 information.

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.127(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under §§ 52.119 or 52.125, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to assure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 50.12(a) are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2\* information, or the technical specifications, or requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is more than a minimal increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is more than a minimal increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.231(a), who believes that an applicant or licensee who references this appendix has not complied with Section VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition, to comply with the general requirements of 10 CFR 2.714(b)(2), the petition must demonstrate that the departure does not comply with Section VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.231 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any

response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with Section VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2\* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.127(a)(4).

b. A licensee who references this appendix may not depart from the following Tier 2\* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

- (1) Maximum fuel rod average burn-up.
- (2) Fuel principal design requirements.
- (3) Fuel criteria evaluation process.
- (4) Fire areas.
- (5) Human factors engineering.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.231(g), depart from the following Tier 2\* matters except in accordance with paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2\* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

- (1) Nuclear Island structural dimensions.

- (2) ASME Boiler and Pressure Vessel Code, Section III, and Code Case N-284.
- (3) Design Summary of Critical Sections.
- (4) ACI 318, ACI 349, and ANSI/AISC--690.
- (5) Definition of critical locations and thicknesses.
- (6) Seismic qualification methods and standards.
- (7) Nuclear design of fuel and reactivity control system, except burn-up limit.
- (8) Motor-operated and power-operated valves.
- (9) Instrumentation and control system design processes, methods, and standards.
- (10) PRHR natural circulation test (first plant only).
- (11) ADS and CMT verification tests (first three plants only).

d. Departures from Tier 2\* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

#### C. Operational requirements.

1. Generic changes to generic technical specifications and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that do require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic technical specifications and other operational requirements are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.758(b) are present. The Commission may modify or supplement generic technical specifications and other operational requirements that were not completely reviewed and approved or require additional technical specifications and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.231(a), who believes that an operational requirement approved in the DCD or a technical specification derived from the generic technical specifications must be changed may petition to admit into the proceeding such a contention. Such petition must comply with the general requirements of 10 CFR 2.714(b)(2) and must demonstrate why special circumstances as defined in 10 CFR 2.758(b) are present, or for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response thereto. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the

plant-specific technical specifications or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic technical specifications have no further effect on the plant-specific technical specifications and changes to the plant-specific technical specifications will be treated as license amendments under 10 CFR 50.90.

*IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)*

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been satisfied.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. In the event that an activity is subject to an ITAAC, and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been satisfied, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC in accordance with Section VIII of this appendix and 10 CFR 52.227(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.227(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the *Federal Register*.

2. In accordance with 10 CFR 52.231(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.231(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a § 52.231(a) hearing, their expiration will occur upon final Commission action in such proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.227 and Section VIII of this appendix.

#### *X. Records and Reporting*

##### A. Records.

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1 and Tier 2. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific

departures made pursuant to Section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting.

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any departures from the plant-specific DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 50.4.

2. An applicant or licensee who references this appendix shall submit updates to its plant-specific DCD, which reflect the generic changes to the generic DCD and the plant-specific departures made pursuant to Section VIII of this appendix. These updates must be filed in accordance with the filing requirements applicable to final safety analysis report updates in 10 CFR 50.4 and 50.71(e).

3. The reports and updates required by paragraphs B.1 and B.2 of this section must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the plant-specific DCD.

b. During the interval from the date of application to the date of issuance of a license, the report and any updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. During the interval from the date of issuance of a license to the date the Commission makes its findings under 10 CFR 52.231(g), the report must be submitted quarterly. Updates to the plant-specific DCD must be submitted annually.

d. After the Commission has made its finding under 10 CFR 52.231(g), reports and updates to the plant-specific DCD may be submitted annually or along with updates to the site-specific portion of the final safety analysis report for the facility at the intervals required by 10 CFR 50.71(e), or at shorter intervals as specified in the license.

## PART 72 - LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

23. The authority citation for Part 72 continues to read as follows:

AUTHORITY: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub.

L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)).  
Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

24. Section 72.210 is revised to read as follows:

§ 72.210 General license issued.

A general license is hereby issued for the storage of spent fuel in an independent spent fuel storage installation at power reactor sites to persons authorized to possess or operate nuclear power reactors under 10 CFR Part 50 or under a combined license or duplicate design license under 10 CFR Part 52 of this chapter.

25. In § 72.218, paragraph (b) is revised to read as follows:

§ 72.218 Termination of licenses.

\* \* \* \* \*

(b) An application for termination of the reactor operating, combined, or duplicate design license submitted under Sec. 50.82 of this chapter must contain a description of how the spent fuel stored under this general license will be removed from the reactor site.

\* \* \* \* \*

**PART 73 - PHYSICAL PROTECTION OF PLANTS AND MATERIALS**

25. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (402 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97 - 425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96 - 295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99 - 399, 100 Stat. 876 (42 U.S.C. 2169).

26. In § 73.1, paragraph (b)(1)(i) is revised to read as follows:

§ 73.1 Purpose and scope.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(i) The physical protection of production and utilization facilities licensed pursuant to 10 CFR Parts 50 or 52 of this chapter,

\* \* \* \* \*

**PART 140 - FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY REQUIREMENTS**

27. The authority citation for Part 140 continues to read as follows:

Authority: Secs. 161, 170, 68 Stat. 948, 71 Stat. 576, as amended (42 U.S.C. 2201, 2210); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

28. In § 140.2, paragraph (a)(1) is revised to read as follows:

§ 140.2 Scope.

(a) \* \* \*

(1) To each person who is an applicant for or holder of a license issued pursuant to 10 CFR Parts 50, 52, or 54 of this chapter to operate a nuclear reactor, and

\* \* \* \* \*

29. Section 140.10 is revised to read as follows:

§ 140.10 Scope.

This subpart applies to applicants for and holders of licenses issued pursuant to 10 CFR Parts 50, 52, or 54 of this chapter authorizing operation of nuclear reactors, except licenses for the conduct of educational activities issued to, or applied for, by persons found by the Commission to be nonprofit educational institutions and except persons found by the Commission to be Federal agencies. This subpart also applies to persons licensed to possess and use plutonium in a plutonium processing and fuel fabrication plant.

30. Section 140.11 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 140.11 Amounts of financial protection for certain reactors.

\* \* \* \* \*

(b) In any case where a person is authorized pursuant to Parts 50 or 52 of this chapter to operate two or more nuclear reactors at the same location, the total primary financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors: *Provided*, That such primary financial protection covers all reactors at the location.

(c) A holder of a combined license issued under Part 52 of this chapter must comply with paragraphs (a) and (b) of this section when the Commission authorizes operation under § 52.231(g).

31. Section 140.13 is revised to read as follows:

§ 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses.

(a) Each holder of a construction permit under Part 50 of this chapter authorizing construction of a nuclear reactor who is also the holder of a license under Part 70 of this chapter authorizing ownership, possession, and storage only of special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of an operating license under Part 50 of this chapter, shall (during the period prior to issuance of the license authorizing operation of the reactor) have and maintain financial protection in the amount of \$1,000,000. Proof of financial protection shall be filed with the Commission in the manner specified in § 140.15 prior to issuance of the license under Part 70 of this chapter.

(b) Each holder of a combined license for a nuclear power reactor under Part 52 of this chapter, who is also the holder of a license under Part 70 of this chapter authorizing ownership, possession, and storage only of special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after authorization to operate under Part 52 of this chapter, shall (during the period prior to Commission authorization to operate the reactor under § 52.231 of this chapter) have and maintain financial protection in the amount of \$1,000,000. Proof of financial protection shall be filed with the Commission in the manner specified in § 140.15 prior to issuance of the license under Part 70 of this chapter.

PART 170 - FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES,

AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954,

AS AMENDED

32. The authority citation for Part 170 continues to read as follows:

Authority: sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701); sec. 301, Pub. L. 92-314, 86 Stat. 227 (42 U.S.C. 2201w); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205a, Pub. L. 101-576, 104 Stat. 2842, as amended (31 U.S.C. 901, 902).

33. In § 170.2, paragraphs (g) and (k) are revised to read as follows:

§ 170.2 Scope.

\* \* \* \* \*

(g) An applicant for or holder of a production or utilization facility construction permit or operating license issued under 10 CFR Part 50 of this chapter, or an approval, certification, permit, or license issued under 10 CFR Part 52 of this chapter;

\* \* \* \* \*

(k) Applying for or already has applied for review, under 10 CFR Part 52, of a facility site prior to the submission of an application for a construction permit;

\* \* \* \* \*

Dated at Rockville, Maryland, this XX day of XXXXX, 2002.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,  
Secretary of the Commission.