



NUCLEAR ENERGY INSTITUTE

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**PROPOSED RULE** *FR 2, 20, 21, 50, 51, 72, 73, 140 + 170*  
*(68FR 40026)*

Dr. Ronald L. Simard  
SENIOR DIRECTOR, NEW PLANT DEPLOYMENT  
NUCLEAR GENERATION DIVISION

September 30, 2003

Annette L. Vietti-Cook  
Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**ATTENTION:** Rulemakings and Adjudications Staff

**SUBJECT:** *Federal Register* Notice 68 FR 40026, July 3, 2003, Notice of Proposed Rule for Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants.

Dear Ms. Vietti-Cook:

On September 16, 2003, the Nuclear Energy Institute (NEI)<sup>1</sup> submitted its major comments and recommendations concerning the subject notice of proposed rulemaking (NOPR), as well as responses to the seven questions posed in Section IV of the NOPR. This letter provides the balance of the industry comments in response to the July 3 *Federal Register* notice.

Enclosure 1 provides detailed comments on the proposed Part 52 and related rule changes, as well as a few comments on the NOPR Supplementary Information. Enclosure 2 provides a mark-up of the proposed rule language consistent with the industry comments. Enclosure 2 also highlights several editorial recommendations that are not identified in Enclosure 1.

<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all companies licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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*SECY-02*

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September 30, 2003  
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If you have any questions concerning the industry comments in either this or our September 16 letter, please contact me ([rls@nei.org](mailto:rls@nei.org) or 202-739-8128) or Russ Bell ([rjb@nei.org](mailto:rjb@nei.org) or 202-739-8087).

Sincerely,

A handwritten signature in black ink, appearing to read "R. Simard". The signature is written in a cursive style with a large initial "R" and a long, sweeping underline.

Ronald L. Simard

Enclosures:

1. Detailed Industry Comments on Part 52 NOPR
2. Recommended Changes for the Language in the Part 52 Proposed Rule

c: James E. Lyons, NRC/NRR

Enclosure 1 – 9/30/03  
 Detailed Industry Comments on Part 52 NOPR

	NOPR Section	NEI Comments	Recommended Rule Language
1.	<p>Part 52            Reorganization</p>	<p>Format change that renumbers existing sections would introduce administrative burdens in documents that previously referenced old section numbers, and create the potential for confusion. We recommend an alternative approach to reformatting the rule that would affect the numbering of only existing Subpart D on Enforcement.</p> <p>See Enclosure 1, Issue 5, of NEI's 9/16/03 letter.</p> <p>This approach would make the final rule consistent with the subparts indicated in the § 52.3 definitions for "early site permit," "design certification" and "combined license," which do not match the organization of the NOPR.</p> <p>For clarity, the rest of the comments in this table reflect the organization of the NOPR, rather than the organization recommended by this comment</p>	<p>Reorganize Part 52 as follows:</p> <ul style="list-style-type: none"> <li>Subpart A – Early Site Permits</li> <li>Subpart B – Standard Design Certification</li> <li>Subpart C – Combined Licenses</li> <li>Subpart D – Early Site Reviews</li> <li>Subpart E – Standard Design Approvals</li> <li>Subpart F – Manufacturing Licenses</li> <li>Subpart G – Duplicate Design Licenses</li> <li>Subpart H – Enforcement</li> </ul>

	NOPR Section	NEI Comments	Recommended Rule Language
2.	21.2	<p>This section would make Part 21 applicable to ESP holders, which is inappropriate as discussed in our response to NOPR Question 7 in Enclosure 2 of NEI's September 16, 2003, letter. This section should be modified to indicate that ESP holders are not subject to Part 21. As discussed in the NOPR Supplementary Information, there is nothing in an ESP that could constitute a possible "defect" in a "basic component" pursuant to the terms and intent of Part 21. Part 21 reporting becomes the responsibility of the COL holder for all safety issues within the scope of the COL application, including site safety issues within the scope of the referenced ESP and design issues within the scope of a referenced design certification.</p> <p>See also comment #16, below.</p>	<p>(a)(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 <del>permit or</del> 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.</p> <p>(b) For persons licensed to construct a facility under either a construction permit issued under Sec. 50.23 of this chapter or a combined license issued under Sec. 52.227 of this chapter, <del>or approved to hold a permit for a site or sites for one or more nuclear power facilities under Sec. 52.24 of this chapter,</del> evaluation of potential defects and failures to comply and reporting of defects and failures to comply under Sec. 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.</p>

	NOPR Section	NEI Comments	Recommended Rule Language
3.	§ 52.3 Definition of "modular design"	The definition of modular design would encompass many existing multiunit sites and thus is too broad to be useful. This definition is unnecessary and should be deleted. The Part 52 sections where this term is used, §§ 52.107(b)(3), 52.211(b)(1) and 52.231(g), are sufficiently clear without being defined in the rule. We expect that appropriate regulatory guidance will assure unambiguous implementation of these requirements.	<del>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.</del>
4.	§ 52.3 Definition of "prototype plant"	Section 52.107(b)(2)(ii) is sufficiently clear without defining "prototype plant" in the rule. We expect that appropriate regulatory guidance will assure unambiguous implementation of these requirements.  See related comments: <ul style="list-style-type: none"> <li>• Comments #34 &amp; 35, below, concerning proposed Section 52.211(b)(3)</li> <li>• See Comment #33, below, and Enclosure 1, Issue 4, of NEI's 9/16/03 letter concerning Section 52.211(b)(1)</li> </ul>	<del>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.</del>
5.	(NEW) § 52.3 Definitions of "site parameters" and "site characteristics"	As discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter), the terms "site characteristics" and "site parameters" should be defined in Section 52.3.	<u>"Site parameters" are the postulated physical, environmental and demographic features of a generalized site assumed for and established in a design certification. A COL application referencing a certified design must contain information demonstrating compliance with the site parameters.</u>  <u>"Site characteristics" are the actual physical, environmental and demographic features of a site. Site characteristics are specified in an early site permit, and a COL application referencing an early site permit must contain sufficient information to demonstrate that the design of the facility falls within the specified site characteristics.</u>

	NOPR Section	NEI Comments	Recommended Rule Language
6.	<p>§ 52.5 Applicability of Part 50 requirements</p>	<p>We strongly disagree with the proposal to broadly sweep all of the requirements of numerous subsections of Part 50 onto applicants, holders and licensees for all seven of the licensing processes described in Part 52.</p> <p>This approach would represent a significant new burden, would create unnecessary and confusing requirements, and the potential for unintended consequences.</p> <p><b>See Enclosure 1, Issue 1, of NEI's 9/16/03 letter for a discussion of the alternative approach recommended by the industry, including use of the alternate rule language at right and development of regulatory guidance that clarifies which NRC requirements are applicable in a particular Part 52 context, and which are not.</b></p> <p>For example, under the industry-recommended approach, ESP application and NRC review guidance would identify that, consistent with the NRC position in its 2/03/03 "ESP-3" letter to NEI and ESP Review Standard RS-002 currently under development, 10 CFR Part 50, Appendix B, is not technically relevant and does not apply to ESP applicants or holders. We envision that such guidance would be developed to support first use of each Part 52 subprocess, e.g., ESP, COL, etc..</p>	<p><u>Applicability of 10 CFR Part 50 provisions</u></p> <p><del>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.</del></p> <p><u>Applicability of NRC requirements</u></p> <p><u>Unless otherwise specifically provided for in 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 10 CFR Chapter I as they apply and are technically relevant to the particular licensing action.</u></p>
7.	52.8(b)	<p>Changes in this section are needed to account for other changes being proposed by NEI.</p>	<p>(b) The approved information collection requirements contained in this part appear in Sections 52.15, 52.17, 52.29, 52.35, 52.39, 52.45, 52.105, 52.107, <del>52.111</del>, 52.119, <u>52.120</u>, 52.121, 52.123, 52.127, 52.205, 52.207, 52.209, 52.211, <del>52.215</del>, 52.223, 52.225, 52.229, 52.231, 52.243, and Appendices A, B, and C.</p>

	NOPR Section	NEI Comments	Recommended Rule Language
8.	§ 52.17(a)(1) Re: use of PPE approach	<p>Based on experience with the pilot ESP applications, modification of proposed Section 52.17(a)(1) is needed to 1) appropriately reflect the acceptability of using bounding design parameters in lieu of actual facility information (i.e., the plant parameters envelope approach), and 2) clarify the nature of dose consequence analyses that must be provided as part of ESP applications.</p> <p>See Enclosure 1, Issue 6, of NEI's 9/16/03 letter for discussion of the industry recommendation.</p> <p>See also Comment #30, below</p>	
9.	§ 52.17(a)(2) Terminology	<p>Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent to refer to the actual characteristics of the site.</p>	<p>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 <u>characteristics of the site parameters</u>, and provided further that ....</p>
10	§ 52.18 Terminology	<p>Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent to refer to the actual characteristics of the site.</p>	<p>In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR Part 51, 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 <u>characteristics of the postulated-site parameters</u>, and provided further that ....</p>

11	§ 52.19 Applicability of NRC requirements	<p>New § 52.19 states that applicants for and holders of ESPs shall comply with all requirements applicable to applicants for construction permits and limited work authorizations under § 50.10. Such a requirement would represent a significant new burden, would create unnecessary and confusing requirements, and create the potential for unintended consequences. Further, only ESPs that include a site redress plan would be subject to Section 50.10. We recommend this section be deleted.</p> <p><b>See Enclosure 1, Issue 1, for a discussion of the alternative approach recommended by the industry.</b></p>	<p><del>(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.</del></p> <p><del>(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.</del></p>
12	§ 52.21 Terminology	<p>Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent to refer to the actual characteristics of the site.</p>	<p>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 <u>characteristics of parameters</u> for the site can be constructed and operated without undue risk to the health and safety of the public.</p>
13	§ 52.21	<p>This section states that an ESP is "subject to all procedural requirements in 10 CFR 2 which are applicable to construction permits." This would include §2.764, "Immediate effectiveness of initial decision directing issuance or amendment of construction permit or operating license," Paragraph (e) of that section states that a licensing board decision authorizing issuance of a construction permit is not effective until the NRC has reviewed the decision. However, this level of Commission involvement is not warranted for a licensing board decision on an ESP because an ESP does not authorize plant construction or any safety-related construction activities.</p> <p>Therefore, it is recommended that Section 52.21 be revised to state that a licensing board decision on an ESP application is immediately effective.</p>	<p>...All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in subpart G of part 2, <u>except that the provisions in 10 CFR 2.764(e) shall not apply to early site permit proceedings.</u></p>

14	§ 52.24 Terminology	Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent that site characteristics are to be specified in the ESP.	The early site permit shall specify the site <u>characteristics parameters</u> and the terms and conditions of the early site permit.
15	§ 52.28 ESP transfers	<p>This proposed requirement for ESP transfers to be processed under 10 CFR 50.80 would require a transfer applicant to provide financial and technical qualification information, even though it is not required of an ESP applicant. Proposed § 52.28 should be modified to clarify that financial and technical qualification information is not required for ESP transfers.</p> <p><b>See also Enclosure 1, Issue 1, of NEI's 9/16/03 letter.</b></p>	<p>§ 52.28 Transfer of early site permits</p> <p>(a) <u>An early site permit, or any right thereunder, shall not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer or control of the permit to any person, unless the Commission shall give its consent in writing.</u></p> <p>(b) <u>An application for transfer of an early site permit shall include information demonstrating that the applicant satisfies the filing requirements of Section 52.15(a).</u></p> <p>(c) <u>The Commission may require any person who submits an application for transfer of an early site permit pursuant to the provisions of this section to file a written consent from the existing holder of the early site permit or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the early site permit.</u></p> <p>(d) <u>After appropriate notice to interested persons, including the existing holder of the early site permit, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of an early site permit, if the Commission determines:</u></p> <ol style="list-style-type: none"> <li>(1) <u>That the proposed transferee satisfies the requirements of this section; and</u></li> <li>(2) <u>That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.</u></li> </ol>

16	§ 52.37	Consistent with comment #2, above, and our response to NOPR Question 7 in Enclosure 2 of NEI's September 16, 2003, letter, this section should be modified to indicate that ESP applicants and holders are not subject to Part 21. As discussed in the NOPR Supplementary Information, there is nothing in an ESP that could constitute a possible "defect" in a "basic component" pursuant to the terms and intent of Part 21. Part 21 reporting becomes the responsibility of the COL holder for all safety issues within the scope of the COL application, including site safety issues within the scope of the referenced ESP and design issues within the scope of a referenced design certification.	For purposes of <del>part 21</del> and 10 CFR 50.100, an early site permit is a construction permit.
17	§ 52.39(a)(2)	Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent that site characteristics are to be specified in the ESP.	... 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 <u>characteristics</u> <del>parameters</del> 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.
18	52.39(a)(2)(i)	Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent that site characteristics are to be specified in the ESP.	A contention that a nuclear reactor does not fit within one or more of the site <u>characteristics</u> <del>parameters</del> included in the early site permit may be litigated in the same manner as other issues material to the proceeding.

19	§ 52.39(b)	<p>This proposed section states that if emergency planning (EP) information is updated for COL, the updated information is subject to NRC review and hearing if the information "materially changes the bases for the Commission's determination" under Section 52.17(b). The proposed threshold for NRC review and hearing on updated EP information is too low and is inconsistent with the intent of this section to provide appropriate finality to matters resolved in the ESP.</p> <p>The industry recommends that updates to EP information be processed using the same threshold for NRC review and hearing as currently exists in 10 CFR 50.54(q), i.e., changes may be made without prior NRC approval if effectiveness of the EP plan is not decreased and compliance with 10 CFR 50.47(b) and Appendix E is maintained.</p> <p>The Statements of Consideration for the final rule should recognize and make clear that NRC review of additional emergency plan details provided in a COL application concerning "major features" approved in a referenced ESP does not open the door to NRC re-review and re-litigation of the major features themselves.</p> <p><b>See also Enclosure 1, Issue 7, of NEI's 9/16/03 letter for a complete discussion of the industry recommendation.</b></p> <p>See also related comment #40, below, regarding Section 52.211(d)(1).</p>	<p>An applicant for a <del>construction permit</del>, [see next comment] operating license, duplicate design license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update and <u>identify changes to correct</u> the information that was provided under § 52.17(b), <u>including a summary of the evaluation of each. Changes determined to decrease the effectiveness of emergency plans approved in the ESP, and new emergency planning information provided in the application, are subject to NRC review and approval 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</u> [see next comment], operating license, duplicate design license, or combined license proceeding in the same manner as other issues material to those proceedings.</p>
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20	§ 52.39(b)	<p>This section would require an applicant for a construction permit, operating license, duplicate design license, or combined license to update emergency planning information approved in a referenced ESP [see previous comment]. This section should be revised to eliminate this requirement for construction permit applicants.</p> <p>The ESP is considered to be a "partial construction permit," and the CP review associated with emergency planning information is accomplished as part of the ESP proceeding. The requirement to submit updated EP information will be satisfied at the OL stage; it is not necessary to also require updated EP information to be submitted with the CP application.</p> <p>While submittal of updated EP information should not be required of CP applicants, at their discretion, CP applicants who reference an ESP may submit updated or additional EP information for NRC review and approval at the CP stage.</p>	<p>An applicant for a <del>construction permit</del>, operating license, duplicate design license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update and ... [ See previous comment ]</p> <p>... must be subject to litigation during the <del>construction permit</del>, operating license, duplicate design license, or combined license proceeding in the same manner as other issues material to those proceedings.</p>
21	§§ 52.41 and 52.49	<p>These sections provide for early review of site suitability issues prior to application for a full construction permit, combined license, or duplicate design license. Because a Subpart A early site permit review is more extensive than a site suitability issue review under Subpart B, it is possible that due to cost, unavailability of specific technical information or other reason, a prospective ESP applicant might first wish to resolve selected site suitability issues via a Subpart B early site review.</p> <p>We see no reason why the regulations should not also provide for ESP applicants to reference Staff Site Reports issued under Subpart B, and we recommend these sections be modified accordingly.</p>	<p>§ 52.41 – 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 <u>early site permits</u>, 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 <u>early site permit applications</u> and 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.</p> <p>§ 52.49 – The NRC staff will not conduct more than one review of site suitability issues with regard to a particular site prior to the full <u>early site permit</u>, construction permit, combined license, or duplicate design license review required by Subpart A of Part 51 of this chapter. The NRC staff may ....</p>

22	§ 52.107(a)(vi)	It is neither necessary nor appropriate to conform the ITAAC requirements for design certification to the ITAAC requirements for combined licenses. The required scope of ITAAC for design certification is different than that for combined licenses. The current rule language is clearer than that proposed because it reinforces the larger scope of ITAAC for combined licenses, which must include ITAAC on emergency planning and the plant specific design, versus ITAAC for design certifications, which do not. The original language in § 52.47 should be retained.	Proposed inspections, tests, analyses, and acceptance criteria (ITAAC) that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a plant that references the design is built and will operate in accordance with the design certification, <del>the provisions of the Act, and the applicable Commission's rules and regulations.</del>
23	NEW § 52.107(c)	Under existing regulations, a DC applicant is required to submit an FSAR by Section 52.107(a)(1)(i) and 10 CFR 50.34(b). To reflect a lesson-learned from the design certification proceeding, Section 52.107 should require a DC applicant to submit a DCD rather than an SAR.	<p>(c) <u>Form of the safety analysis in the application</u></p> <p>(1) <u>In substitution for the final safety analysis report required by 10 CFR 50.34(b), the application for a standard design certification shall contain a generic design control document containing Tier 1 and Tier 2 information.</u></p> <p>(2) <u>Tier 1 is the portion of the design-related information contained in the generic DCD that is approved and certified. The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:</u></p> <ul style="list-style-type: none"> <li>(i) <u>Definitions and general provisions;</u></li> <li>(ii) <u>Design descriptions;</u></li> <li>(iii) <u>Inspections, tests, analyses, and acceptance criteria (ITAAC);</u></li> <li>(iv) <u>Significant site parameters; and</u></li> <li>(v) <u>Significant interface requirements.</u></li> </ul> <p>(3) <u>Tier 2 is the portion of the design-related information contained in the generic DCD that is approved but not certified. Tier 2 information includes:</u></p> <ul style="list-style-type: none"> <li>(i) <u>Remaining information required by 10 CFR 52.107, with the exception of generic technical specifications, conceptual design information, and the probabilistic risk assessment;</u></li> <li>(ii) <u>Information required for a final safety analysis report under 10 CFR 50.34; and</u></li> <li>(iii) <u>Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met.</u></li> </ul>

24	§ 52.111	<p>Proposed § 52.111 states that design certification applicants must comply with all requirements in 10 CFR applicable to applicants for construction permits and operating licenses under Title 10. Design certification applicants should not be subject to requirements governing operating licenses. Such a requirement would represent a significant new burden, would create unnecessary and confusing requirements, and create the potential for unintended consequences.</p> <p>Moreover, proposed Section 52.111 conflicts with Section 52.107(a)(1)(i) which appropriately qualifies the information required in a design certification application to that which is technically relevant to the design and not site-specific. We recommend deletion of this section.</p> <p>See Enclosure 1, Issue 1, of NEI's 9/16/03 letter for a discussion of the alternative approach recommended by the industry.</p>	<p><del>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.</del></p>
25	NEW § 52.120	<p>Part 52 should explain how a design certification may be used by a construction permit application.</p>	<p>(a) <u>A standard design certification may be referenced by an applicant for a combined license or by an applicant for a construction permit or operating license under 10 CFR part 50.</u></p> <p>(b) <u>The inspections, tests, analyses and acceptance criteria in a standard design certification are not applicable to an applicant for a part 50 construction permit who references the certification. Prior to issuing an operating license, the Commission shall provide an opportunity for hearing on whether, and shall find that, construction of the plant has been completed in conformity with Tier 1, exclusive of ITAAC, and Tier 2 of the plant-specific design control document, as modified and supplemented to reflect the applicant's exemptions and departures.</u></p>

26	<p>§ 52.127(a)(1) and (NEW) § 52.127(d)</p>	<p>To permit the vendor to make generic changes to a design certification that enhance plant economics, reliability and safety, the industry recommends adoption of an additional design certification change process. Such a process is important to permit changes to the standard design prior to any license application referencing the design, thus promoting standardization. Establishing the acceptability of key design changes may be an important factor for power companies considering whether or not to proceed with a project.</p> <p>See Enclosure 1, Issue 3, of NEI's 9/16/03 letter for a full discussion of the industry recommendation.</p>	<p>(a)(1) Notwithstanding any provision in 10 CFR 50.109 <u>and except as provided in paragraph (d) of this section</u>, while a standard design certification is in effect under § 52.55 or 52.61, the Commission may not modify, rescind, or impose new requirements on the certification, ....</p> <p>d) <u>The applicant for the standard design certification issued under this Subpart may file a request for an amendment to the design certification by way of notice and comment rulemaking. 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 the amendment. 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 shall be filed in accordance with § 52.45 and 52.47 of this part. The amendment will apply to construction permits or combined licenses that reference the standard design certification and that are issued after the effective date of the amendment.</u></p>
27	<p>§ 52.127(b)(2)</p>	<p>For consistency with the design certification change process, this section should also identify that an applicant or licensee may make changes within the scope of the referenced design certification in accordance with the applicable change processes for that rule.</p>	<p>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. <u>An applicant or licensee may make changes within the scope of the referenced design certification in accordance with the applicable change processes for that rule. The applicant and 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.</u></p>

28	§ 52.209	Consistent with 10 CFR 50.120, this section should be modified to require the Training Program to be established, implemented and maintained no later than 18 months prior to actual – not scheduled – fuel load. The proposed change avoids potential confusion due to the fact that schedules change and the scheduled fuel load date 18 months in advance may differ from the scheduled fuel load date identified in the Section 52.231(a) notice of intended operation.	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 <u>fuel load</u> the <del>scheduled date for initial loading of fuel, as provided for in § 52.231(a).</del>
29	§ 52.211(a)(1)	Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent that site characteristics are to be specified in the ESP.	(i) Information sufficient to demonstrate that the design of the facility falls within the site <u>characteristics</u> parameters specified in the early site permit;
30	§ 52.211(a)(1)	As discussed in Enclosure 1, Issue 6, of our September 16, 2003, response to NOPR, this section should be modified to reflect that in the case of an ESP based on a specific plant design, the demonstration that the design of the proposed facility falls within the site characteristics may be accomplished in the ESP itself.	(i) Information sufficient to demonstrate that the design of the facility falls within the site <u>characteristics</u> parameters specified in the early site permit, <u>unless this information was approved in connection with the early site permit.</u>
31	§ 52.211(a)(1)	Consistent with our September 16, 2003, response to NOPR question #3, Part 52 should reflect that some terms and conditions of an ESP may not be applicable until after issuance of the COL.	(iii) A demonstration that all terms and conditions of the early site permit have been <u>satisfied or that there is reasonable assurance that all terms and conditions will be satisfied during the term of the combined license.</u>

32	§ 52.211(b)	<p>The proposed rule would add the words "in a final safety analysis report" to the end of this section, however, the motivation for the change is not explained in the NOPR supplementary information. There are two possible interpretations for the change, both of which are contrary to the understood intent of this provision. The first is that COL applicants are required to provide only the information required by 10 CFR 50.34(b). This would exclude the physical security plan required by § 50.34(c), safeguards contingency plan required by § 50.34(d) and other information required of license applicants by § 50.34.</p> <p>A second possible interpretation is that all of the information required by § 52.211(b) is to be contained "in a final safety analysis report."</p> <p>We do not believe either of these interpretations is appropriate or intended by the NRC staff. The words "in a final safety analysis report" are unnecessary and potentially confusing and should be deleted from Section 52.211(b) for the final rule.</p>	<p>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.</p>
33	§ 52.211(b)(1)	<p>The industry objects to the proposal to require that a COL application for a non-certified design be subject to the same testing required for a design certification.</p> <p><b>See Enclosure 1, Issue 4, of NEI's 9/16/03 letter for a complete discussion of this issue.</b></p>	<p>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).</p>
34	§ 52.211(b)(3)	<p>Proposed Section 52.211(b)(3) states that additional requirements may be imposed upon prototype plants related to siting, safety features or operational conditions. The proposed requirement is not necessary because the NRC already has the responsibility and authority under 10 CFR 50.34(b) to obtain sufficient information from applicants to support required safety findings on the design. The NRC recently used this authority to require a containment spray system on the AP600 design even though safety analyses demonstrated that the system was not required to meet Part 100 requirements or assure adequate protection of the public health and safety.</p>	<p><del>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.</del></p>

35	§ 52.211(b)(3)	<p>If, notwithstanding the previous comment, the Commission decides to retain proposed Section 52.211(b)(3) for the final rule, the provision should not permit additional requirements to be imposed for reasons of plant protection. Protection of the physical plant is the purview of the plant owner and is outside the mandate of the NRC to assure adequate protection of the public health and safety.</p> <p>The recommended change should be reflected in the Section 52.3 definition of "prototype plant," if the Commission determines that that term should be defined in the rule. See Comment #4, above.</p>	<p>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 <u>and</u> the plant staff, <del>and the plant itself</del> from the possible consequences of failures during the testing period.</p>
36	§ 52.211(b)(4)	<p>Clarification is necessary to make this section consistent with the design certification rules and distinguish among the COL application, generic DCD, the plant-specific DCD and the FSAR. The proposed rule states that an application referencing a certified design must include in the FSAR the information approved for incorporation by reference in a design certification rule (i.e., the generic DCD). However, the generic DCD is not required or intended to be included in the FSAR. Rather, the DCR appendix, which includes the generic DCD, will be incorporated by reference in a COL application per Section IV.A.1 of the DCRs, and the COL application will include a plant-specific DCD that reflects departures and exemptions from the generic DCD. The FSAR will contain the site-specific information outside the scope of the referenced design certification. This clarification is most efficiently made by referencing to the additional requirements in Section IV.A of the DCRs.</p> <p>Because procurement specifications and construction and installation specifications are not required to be included in either the FSAR or the application referencing the design certification rule, the last part of proposed Section 52.211(b)(4) should be relocated to a new Section 52.211(c) as indicated below.</p>	<p>An application referencing a certified design must <u>satisfy the additional requirements in Section IV.A of that rule.</u> <del>include in the final safety analysis report the information approved for incorporation by reference in a design certification rule;</del> <u>The final safety analysis report must include a site-specific portion that describes 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,; and demonstrates 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).</u></p>

37	§ 52.211(b)(5)	<p>This proposed section would require submission of a plant-specific PRA that would update the design-specific PRA to include site-specific design features and "any" design changes. Because there may be many design changes that do not affect the design-specific PRA and need not be reflected in the plant-specific PRA, it is important that the requirement to include "any design changes" in the plant-specific PRA be clarified.</p>	<p>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 <u>any design changes that affect the design-specific PRA.</u></p>
38	(NEW) § 52.211(c)	<p>Because procurement specifications and construction and installation specifications are not required to be included in either the FSAR or the application referencing the design certification rule, the last part of proposed Section 52.211(b)(4) should be relocated to a new Section 52.211(c).</p>	<p><u>The applicant shall have available for audit procurement specifications and construction and installation specifications in accordance with §§ 52.107(a)(2) and 52.203(b).</u></p>
39	(Proposed) § 52.211(c)(2)	<p>This section should reflect that the context is a COL application that references a design certification. If there is no reference to a design certification, there are no "required" ITAAC until after the COL issues and thus no special notification by either the applicant or NRC (in the FRN required by Section 52.217) is necessary.</p> <p>Consistent with our Comment #45 on Section 52.229(e), the last sentence of this section should be modified to reflect that the <i>Federal Register</i> notification required by § 52.217 must also identify that the NRC staff has verified the successful completion of ITAAC.</p> <p>The rule language should also account for the potential need for a supplemental <i>Federal Register</i> notification in the event that the NRC has not completed its verification of successful ITAAC completion at the time of the Section 52.217 notice of hearing.</p>	<p><u>If the application references a certified standard design, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The NRC staff shall verify that the inspection, test, or analysis identified by the licensee has been successfully completed and, based solely thereon, conclude the prescribed acceptance criteria have been met. The <i>Federal Register</i> notification required by § 52.217, or supplement thereto, must indicate that the application includes this notification and that the NRC has concluded that the prescribed acceptance criteria have been met.</u></p>

40	<p>§ 52.211(d)(1)</p>	<p>This proposed section states that if emergency planning (EP) information approved in a referenced ESP is updated for COL, the updated information is subject to NRC review and hearing if the information "materially changes the bases for the Commission's determination" under Section 52.17(b).</p> <p>The proposed threshold for NRC review and hearing on updated EP information is too low and is inconsistent with the intent of Section 52.39(a) to accord appropriate finality to matters resolved in the ESP, including emergency planning information.</p> <p>The industry recommends that updates to EP information be processed using the same threshold for NRC review and hearing as currently exists in 10 CFR 50.54(q), i.e., changes may be made without prior NRC approval if effectiveness of the EP plan is not decreased and compliance with 10 CFR 50.47(b) and Appendix E is maintained.</p> <p>The Statements of Consideration for the final rule should recognize and make clear that NRC review of additional emergency plan details provided in a COL application concerning "major features" approved in a referenced ESP does not open the door to NRC re-review and re-litigation of the major features themselves.</p> <p>See also Enclosure 1, Issue 7, of NEI's 9/16/03 letter for a complete discussion of the industry recommendation.</p> <p>See also related Comment #19, above.</p>	<p>An applicant for a <del>construction permit</del>, <u>[see Comment 20, above]</u> operating license, duplicate design license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update and <u>identify changes to correct</u> the information that was provided under § 52.17(b), <u>including a summary of the evaluation of each. Changes determined to decrease the effectiveness of emergency plans approved in the ESP, and new emergency planning information provided in the application, are subject to NRC review and approval 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</u>, <u>[see Comment 20, above]</u> operating license, duplicate design license, or combined license proceeding in the same manner as other issues material to those proceedings.</p>
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41	§ 52.215	As discussed in Enclosure 1, Issue 1, of our September 16, 2003, response to the NOPR, we strongly recommend an alternative approach to address the issue of applicability of Part 50 and other NRC requirements to COL applicants and holders. Coupled with the alternative language recommended for Section 52.5, we envision that the effectiveness of operating license requirements after operation is authorized under Section 52.231 would be addressed by a license condition.	<p><del>_____ (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.</del></p> <p><del>_____ (b) After a combined license is issued but before the Commission has authorized operation under Sec. 52.231, the licensee shall comply with all requirements in this chapter of Title 10 applicable to holders of construction permits for nuclear power reactors.</del></p> <p><del>_____ (c) After the Commission has authorized operation under Sec. 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 Sec. Sec. 50.55(a), (b) and (d), and 50.58(a).</del></p>
42	§ 52.221	Part 52 should be modified to reflect consistent use of the terms "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 of NEI's 9/16/03 letter). In this case, the term "site parameters," is inconsistent with the intent that site characteristics are to be specified in the ESP.	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 <u>characteristics</u> 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.

43	§ 52.225(a)	Editorial comment for clarity: As written, it is not clear that exemptions involving any part of a design certification rule must satisfy both the requirements of 10 CFR 50.12(a) and the additional requirements of Section 52.127(b)(1).	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) <del>or 52.127(b)(1)</del> <u>and</u> , if the exemption includes any part of the design certification rule, <u>that the additional requirements of Section 52.127(b)(1) are met.</u>
44	§ 52.227(c) and (d)(2)	We recommend that these sections be modified to reflect that the applicable change process for fire protection system/program changes that do not involve or affect information approved in a design certification is the standard fire protection license condition.	<p>(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) <u>or the license.</u></p> <p>(d)(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 <u>or the license</u> 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.</p>

45	§ 52.229 (e)	<p>We recommend that Section 52.229(e) be conformed fully to match the language established in the design certification rules.* The language approved by the Commission for Section IX.B.1 of the DCRs clarified the Commission's intent under existing Section 52.99 that the NRC staff is to verify that ITAAC have been met and publish notices of successful ITAAC completion. Conforming Section 52.229(e) and the DCRs ensures that the Commission intent regarding NRC staff ITAAC verification is uniformly reflected throughout Part 52, including current and future design certification appendices. Adopting this language for Section 52.229(e) would also be consistent with the Commission's direction in their SRM on SECY-02-0077 to preserve the original intent of this provision.</p> <p><b>See Enclosure 1, Issue 2, of NEI's 9/16/03 letter for a complete discussion of this recommendation.</b></p> <p>*One slight change is recommended to Section IX.B.1 of the DCRs to better distinguish between NRC staff ITAAC <u>conclusions</u> under Section 52.229(e) and the Commission's ITAAC <u>finding</u> under Section 52.231(g). See comment #58, below.</p>	<p>The NRC staff shall ensure that the required inspections, tests, and analyses in the ITAAC are performed <u>and, prior to operation of the facility, shall conclude that the prescribed acceptance criteria are met. The NRC staff shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find conclude the prescribed acceptance criteria have been met.</u> At appropriate intervals during construction, the NRC shall publish notices in the <i>Federal Register</i> of the successful completion of inspections, tests and analyses.</p>
46	52.231(h)	<p>Editorial changes for clarity</p>	<p>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. <u>Except for specific ITAAC, which that are the subject of a hearing under paragraph (a) of this section, their expiration ITAAC will expire occur</u> 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.</p>

47	52.249	As discussed in Enclosure 1, Issue 1, of our September 16, 2003, response to the NOPR, we recommend an alternative approach to address the issue of applicability of Part 50 and other NRC requirements to Part 52 applicants, licensees and holders.	<del>An applicant shall comply with all requirements in this chapter of Title 10 applicable to applicants for construction permits and operating licenses under this chapter of Title 10, except §§ 50.10(b) and (c), 50.12(b), 50.23, 50.30(d), 50.34(a)(10), 50.34a(e), 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.</del>
48	52.255	The duration of the design approval should be 15 years to be consistent with the duration of final design approvals and design certifications.	A nuclear plant design that is approved as part of the issuance of a manufacturing license is valid for <del>five</del> fifteen years from the date of issuance of the manufacturing license.
49	52.403(b)	The Part 52 sections identified as not issued under sections 161b, 161i, or 161o for the purposes of section 223 should be revisited by the NRC staff and the basis for selective identification sections explained. For example, why are the sections in new Part 52 subparts B, D, H and I excluded? At a minimum, this section should be modified to include additional sections of Part 52, including its appendices.	(b) The regulations in this part 52 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223. are as follows: Sections 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, <u>52.35</u> , 52.37, 52.39, 52.101, 52.103, 52.105, 52.107, 52.109, 52.111, 52.113, 52.115, 52.117, 52.119, <u>52.120</u> , 52.121, 52.123, 52.125, <u>52.127</u> , 52.201, 52.203, 52.205, 52.207, 52.209, 52.211, 52.213, 52.215, 52.217, 52.219, 52.221, <u>52.223</u> , 52.225, 52.227, <u>52.229</u> , 52.231, 52.401, 52.403 <u>and Appendices A, B and C.</u>
50	ABWR DCR, Section V.B.4	ABWR DCR Section V.B inadvertently omitted reference to an exemption granted by the NRC in certifying the ABWR.	<u>Appendix A to 10 CFR part 100 - - Operating Basis Earthquake</u>
51	DCR II.E.1	The design specific PRA is a requirement of Section 52.107 that, like the generic technical specifications and conceptual design information, is also not considered part of Tier 2. The definition of Tier 2 should be modified accordingly.	Information required by 10 CFR 52.107, with the exception of generic technical specifications, <u>the design-specific PRA</u> and conceptual design information;

52	(NEW) DCR II.G	<p>Consistent with adding the definition of "departure from a method of evaluation," the basic definition of "departure" should also be added to the DCRs. Like the definition of "departure from a method of evaluation," the definition of "departure" should be based on that from Regulatory Guide 1.187. The basic definition of "change or departure" should precede the definition of "departure from a method of evaluation," so we recommend adding the new definition as paragraph II.G and renaming the final two paragraphs as II.H and II.I.</p> <p>We also recommend that the Statements of Consideration for the final rule refer readers to the source of these definitions and guidance on their use contained in NEI 96-07, <i>Guidelines for 10 CFR 50.59 Implementation</i>, Revision 1, which was endorsed by Regulatory Guide 1.187.</p>	<p><u>Change or departure means a modification or addition to, or removal from, the facility or procedures that affects: (1) a design function, (2) method of performing or controlling the function, or (3) an evaluation that demonstrates that intended functions will be accomplished.</u></p>
53	DCRs III.E	<p>Part 52 should be modified to reflect consistent use of terminology related to "site characteristics" and "site parameters," as discussed in response to Stakeholder Question 2.1 (Enclosure 2 to NEI's 9/16/03 letter). In this case, the term "site-specific design parameters," refers to the characteristics of the specific site for which design activities outside the scope of the DCR may be performed.</p>	<p>Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site-specific <del>characteristics-specific design parameters</del>, provided the design activities do not affect the DCD or conflict with the interface requirements.</p>

54	DCRs IV.A	<p>We recommend the following modifications of Section IV of the DCRs:</p> <ol style="list-style-type: none"> <li>1. Section IV.A.2 should be modified to indicate that the items (a) through (f) are to be "physically" included in the application to be consistent with the language of Section IV.A.3.</li> <li>2. Section IV.A.2.a should be clarified so that it does not say that the plant-specific DCD must contain the "same" information as the generic DCD</li> <li>3. Section IV.A.2.b should be clarified to reflect that until the day an application referencing a generic DCD is submitted, there is no plant-specific DCD, and thus there can be no report on departures from it. The report (singular) provided on the day the application is submitted will identify departures from the generic DCD. See also related comment #60, below regarding Section X.B reporting requirements.</li> </ol>	<p>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:</p> <ol style="list-style-type: none"> <li>1. Incorporate by reference, as part of its application, this appendix;</li> <li>2. <u>Physically include</u>, as part of its application: <ol style="list-style-type: none"> <li>a. A plant-specific DCD containing the <u>generic DCD same information for the XYZ design</u> and utilizing the same organization and numbering as the generic DCD <del>for the U.S. XYZ design</del>, as modified and supplemented by the applicant's exemptions and departures;</li> <li>b. The reports on departures from <u>the generic DCD</u> and updates to the plant-specific DCD required by Section X.B of this appendix;</li> <li>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;</li> <li>d. Information demonstrating compliance with the site parameters and interface requirements;</li> <li>e. Information that addresses the COL action items; and</li> <li>f. Information required by 10 CFR 52.107(a) that is not within the scope of this appendix.</li> </ol> </li> <li>3. Physically include, in the plant-specific DCD, the proprietary information and safeguards information referenced in the XYZ DCD.</li> </ol>
55	DCRs VIII.B.6.a	<p>As identified in Section VIII.B.6.b, departures from Tier 2* information are requested and approved via the 10 CFR 50.90 license amendment process. Section VIII.B.6.a should be modified to be consistent with Section VI.B.5 which provides that "all [plant-specific] departures from the DCD that are approved by license amendment" are considered resolved within the meaning of Section 52.127(a)(4).</p>	<p>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. <del>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).</del></p>

56	DCRs VIII.C.3	<p>This section should be revised to require that the NRC satisfy the backfit requirements in 10 CFR 50.109 in order to require a plant-specific departure from the generic technical specifications or operational requirements approved in the design certification.</p>	<p>The Commission may require plant-specific departures on generic technical specifications and other operational requirements that were completely reviewed and approved, provided <u>the change satisfies the requirements of 50.109, and 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. ...</u></p>
57	DCRs VIII.C.4	<p>This section should be amended in three respects. First, there should be recognition, like that in paragraph C.3, that not all operational requirements identified in Tier 2 were completely reviewed and approved by the NRC. The determination of whether an operational requirement (e.g., related to ISI/IST, surveillance testing or post-fuel load verification) was completely reviewed and approved is based on review of the NRC safety conclusion in the applicable FSER. Operational requirements that were not completely reviewed and approved by the NRC should not be subject to any Tier 2 change controls.</p> <p>Second, there is no basis to require a more burdensome change control process (10 CFR 50.12) for NRC-approved operational requirements than is required for design requirements in Tier 2 (the "50.59-like" process). Accordingly, this section should be modified to reflect that plant-specific departures from NRC-approved operational requirements are controlled via the Section VIII.B.5 "50.59-like" process in the same way as other Tier 2 information.</p> <p>And third, consistent with Comment #55, above, and Section VI.B.5 of the design certification rules, this section should be modified to reflect that "all [plant-specific] departures from the DCD that are approved by license amendment" are considered resolved within the meaning of Section 52.127(a)(4).</p>	<p>An applicant who references this appendix may request an exemption from the generic technical specifications or other operational requirements. <u>A departure from an operational requirement that was completely reviewed and approved in the design certification rulemaking does not require an exemption unless the departure requires Commission approval under VIII.B.5 of this appendix.</u> <del>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). If an exemption is required, the grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.</del> <u>Information concerning operational requirements that was not completely reviewed and approved in the design certification rulemaking must be subject to litigation in the same manner as other issues material to the license hearing.</u></p>

58	DCRs IX.B.1	We recommended clarification of Section IX.B.1 of the DCRs to better distinguish between NRC staff ITAAC <u>conclusions</u> under Section 52.229(e) and the Commission's ITAAC <u>finding</u> under Section 52.231(g).	The NRC staff shall ensure that the required inspections, tests, and analyses in the ITAAC are performed and, prior to operation of the facility, shall conclude that the prescribed acceptance criteria are met . The NRC staff shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, <del>find</del> <u>conclude</u> 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.
59	DCRs IX.B.3	Editorial change for clarity	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. <u>Except for specific ITAAC, which that</u> are the subject of a § 52.231(a) hearing, <del>their expiration-ITAAC will expire occur</del> 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.

60	DCRs X.B	<p>Section X.B.1 and X.B.3 should be clarified to reflect that until the day an application referencing a generic DCD is submitted, there is no plant-specific DCD, and thus there can be no report on departures from it. The report (singular) provided on the day the application is submitted will identify departures from the generic DCD.</p>	<p>X.B.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 <u>generic plant-specific DCD</u>, 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.</p> <p>3. The reports and updates required by paragraphs B.1 and B.2 of this section must be submitted as follows:</p> <p>a. On the date that an application for a license referencing this appendix is submitted, the application must include the report <u>on departures from the generic and any updates to the plant-specific DCD</u>.</p>
61	§171.15(a)	<p>This section should be amended to indicate that a COL holder is not required to pay annual fees until the Commission makes its finding under 52.231(g).</p>	<p>Each person licensed to operate a power, test, or research reactor <u>under part 50 or under part 52 after the Commission makes the finding specified in 10 CFR 52.231</u>; each person holding a part 50 or part 52 power reactor license that is in decommissioning or possession only status, except those that have no spent fuel on-site; and each person holding a part 72 license who does not hold a part 50 or part 52 licensee shall pay the annual fee for each license held at any time during the Federal FY in which the fee is due. This paragraph does not apply to test and research reactors exempted under § 171.11(a).</p>

**Comments on Supplementary Information**

1.	Page 40029	This page contains a typo. The reference in the center column to Section 52.21 should be to Section 52.211.
2.	Page 40035	This page states that the Commission will make the 52.231(g) finding to authorize fuel load. We recommend that this discussion be modified to reflect that the Commission, at its discretion, may delegate the responsibility for the 52.231(g) finding to the NRC staff. Giving the NRC staff this authority would result in a more efficient and flexible process leading to fuel load.
3.	Page 40036	This page contains a typo. The reference in the right-hand column to Section 52.111 should be to Section 52.19.

## ENCLOSURE 2

### RECOMMENDED CHANGES FOR THE LANGUAGE IN THE PROPOSED RULE

Note: As discussed in Enclosure 1, Issue 5, of NEI's September 16, 2003, response to the NOPR, in addition to the following changes, NEI also recommends that the section numbers in Part 52 be revised to be consistent with the original numbering system in Part 52.

#### 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 Sec. 2.110, paragraph (a) is revised to read as follows:

**Sec. 2.110 Filing and administrative action on submittals for ~~standard design approvals review or early site reviews~~ of site suitability issues.**

(a)(1) A submittal under subpart E of part 52 of this chapter must be subject to Sec. Sec. 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 Sec. 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:

**Sec. 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:

**Sec. 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 Sec. 50.22 of this chapter, the Secretary will issue notices of hearing under Sec. 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 Sec. 2.402, paragraph (a) is revised to read as follows:

**Sec. 2.402 Separate hearings on separate issues; consolidation of proceedings.**

(a) In the case of applications under subpart I of part 52 of this chapter for construction permits for nuclear power reactors of a type described in Sec. 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:**

**Sec. 2.403 Notice of proposed action on applications for operating licenses under 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 Sec. 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:**

**Sec. 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 Sec. 2.402.

**8. Section 2.406 is revised to read as follows:**

**Sec. 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:**

**Sec. 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 Sec. 2.501, paragraphs (a), (b)(1)(vii) and (b)(3) are revised to read as follows:

**Sec. 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 Sec. 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 Sec. 52.245(b) of this chapter,

\* \* \* \* \*

11. Section 2.502 is revised to read as follows:

**Sec. 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 Sec. 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:

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

Sec. 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 Sec. 50.23 of this chapter or a combined license issued under Sec. 52.227 of this chapter, ~~or approved to hold a permit for a site or sites for one or more nuclear power facilities under Sec. 52.24 of this chapter,~~ evaluation of potential defects and failures to comply and reporting of defects and failures to comply under Sec. 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 Sec. Sec. 50.72, 50.73 or Sec. 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:

Sec. 21.3 Definitions.

As used in this part:

Basic component. (1)(i) 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:

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

or

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

(ii) 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.

(2) 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.

(3) 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. (1) 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).

(2) 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:

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

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

(iii) 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. The dedicating entity, pursuant to Sec. 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.** (1) 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.

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

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

(3) 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

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued 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 Sec. 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:

Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in Sec. 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 must 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 Sec. 50.8, paragraph (b) is revised to read as follows:

Sec. 50.8 Information collection requirements: OMB approval.

\* \* \* \* \*

(b) The approved information collection requirements contained in this part appear in Sec. Sec. 50.30, 50.33, 50.33a, 50.34, 50.34a, 50.35, 50.36, 50.36a, 50.36b, 50.44, 50.46, 50.47, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.60, 50.61, 50.62, 50.63, 50.64, 50.65, 50.66, 50.68, 50.71, 50.72, 50.74, 50.75, 50.80, 50.82, 50.90, 50.91, 50.120, and appendices A, B, E, G, H, I, J, K, R, and S to this part.

\* \* \* \* \*

19.5 In Sec. 50.55a(h)(3), the reference to 10 CFR Part 52, Appendix O, should be replaced with a reference to 10 CFR Part 52, subpart E.

\* \* \* \* \*

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

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

\* \* \* \* \*

Appendix M to Part 50 [Removed]

21. Appendix M to Part 50 is removed.

Appendix N to Part 50 [Removed]

22. Appendix N to Part 50 is removed.

Appendix O to Part 50 [Removed]

23. Appendix O to Part 50 is removed.

Appendix Q to Part 50 [Removed]

24. Appendix Q to Part 50 is removed.

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

25. 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)).

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

Sec. 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.

\* \* \* \* \*

~~26.5 The references in Sections 51.54, 51.55(b), 51.76 and 51.77 to 10 CFR Part 52, Appendix M, should be replaced with references to 10 CFR Part 52, subpart H.~~

\* \* \* \* \* to 10 CFR Part 52,

27. Part 52 is revised to read as follows:

**PART 52--ADDITIONAL LICENSING PROCESSES FOR NUCLEAR POWER PLANTS**

**General Provisions**

Sec.

52.1 Scope.

52.3 Definitions.

~~52.5 Applicability of NRC requirements 10 CFR Part 50 provisions.~~

52.8 Information collection requirements: OMB approval. Subpart A--Early Site Permits

52.11 Scope of subpart.

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

52.15 Filing of applications.

52.17 Contents of applications.

52.18 Standards for review of applications.

~~52.19 Applicability of NRC requirements.~~

52.21 Hearings. 52.23 Referral to the ACRS.

- 52.24 Issuance of early site permit.
- 52.25 Extent of activities permitted.
- 52.27 Duration of permit.
- 52.28 Transfer of early site permit.
- 52.29 Application for renewal.
- 52.31 Criteria for renewal.
- 52.33 Duration of renewal.
- 52.35 Use of site for other purposes.
- 52.37 Reporting of defects and noncompliance; revocation, suspension, modification of permits for cause.
- 52.39 Finality of early site permit determinations. Subpart B--Early Site Reviews
- 52.41 Scope of subpart.
- 52.43 Filing and contents of applications.
- 52.45 Notice of application.
- 52.46 Referral to the ACRS.
- 52.47 Issuance of site report.
- 52.49 Relationship to other subparts. Subpart C--[Reserved] Subpart D--Standard Design Certifications
- 52.101 Scope of subpart.
- 52.103 Relationship to other subparts.
- 52.105 Filing of applications.
- 52.107 Contents of applications.
- 52.109 Standards for review of applications.
- ~~52.111 Applicability of NRC requirements.~~
- 52.113 Administrative review of applications.
- 52.115 Referral to the ACRS.
- 52.117 Issuance of standard design certification.
- 52.119 Duration of certification.
- ~~52.120 Referencing a standard design certification~~
- 52.121 Application for renewal.
- 52.123 Criteria for renewal.
- 52.125 Duration of renewal.
- 52.127 Finality of standard design certifications.
- Subpart E--Standard Design Approvals
- 52.131 Scope of subpart.
- 52.133 Filing of applications.
- 52.135 Contents of applications.
- 52.137 Referral to the ACRS.
- 52.139 Staff approval of design.
- 52.141 Finality of the design approval.
- 52.143 Information requests.
- Subpart F--[Reserved] Subpart G--Combined Licenses
- 52.201 Scope of subpart.
- 52.203 Relationship to other subparts.

52.205 Filing of applications.  
52.207 Contents of applications; general information.  
52.209 Contents of applications; training and qualification of nuclear power plant personnel.  
52.211 Contents of applications; technical information.  
52.213 Standards for review of applications.  
~~52.215 Applicability of NRC requirements.~~  
52.217 Administrative review of applications.  
52.219 Referral to the ACRS.  
52.221 Environmental review.  
52.223 Authorization to conduct site activities.  
52.225 Exemptions and variances.  
52.227 Issuance of combined licenses.  
52.229 Inspection during construction.  
52.231 Operation under a combined license. Subpart H--Manufacturing Licenses  
52.241 Scope of subpart.  
52.243 Relationship to other subparts.  
52.245 Filing and contents of applications.  
52.247 Standards for review of applications.  
~~52.249 Applicability of NRC requirements.~~  
52.251 Referral to the ACRS.  
52.253 Issuance of manufacturing license.  
52.255 Duration of design approval.  
52.257 Finality of the manufacturing license.  
Subpart I--Duplicate Design Licenses  
52.261 Scope of subpart.  
52.263 Relationship to other subparts.  
52.265 Filing and contents of applications.  
Subpart J--[Reserved]  
Subpart K--[Reserved]  
Subpart L--[Reserved]  
Subpart M--Enforcement  
52.401 Violations.  
52.403 Criminal penalties.  
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

Sec. 52.1 Scope.

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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.

### Sec. 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 **G G** 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 Sec. 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.

Site characteristics are the actual physical, environmental, and demographic features of the proposed facility location that are specified in an early site permit. A COL application referencing an early site permit must contain sufficient information to demonstrate that the design of the facility falls within the specified site characteristics.

Site parameters are the postulated physical, environmental, and demographic features of a generalized site assumed for and established in a design certification. A COL application referencing a certified design must contain information demonstrating compliance with the site parameters.

Standard design means a design which is sufficiently detailed and complete to support certification in accordance with subpart **D 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 **D 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.

~~Sec. 52.5 Applicability of NRC requirements 10 CFR part 50 provisions.~~

~~Unless otherwise specifically provided for in this part, Sec. Sec. 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.~~

~~Unless otherwise specifically provided for in 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 10 CFR Chapter I as they apply and are technically relevant to the particular licensing action.~~

**Sec. 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 Sec. Sec. 52.15, 52.17, 52.29, 52.35, 52.39, 52.45, 52.105, 52.107, ~~52.111~~, 52.119, 52.120, 52.121, 52.123, 52.127, 52.205, 52.207, 52.209, 52.211, ~~52.215~~, 52.223, 52.225, 52.229, 52.231, 52.243, and Appendices A, B, and C.

**Subpart A--Early Site Permits**

**Sec. 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.

**Sec. 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 of this part 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 of this part 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. This 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.

#### Sec. 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.

#### Sec. 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 Sec. 50.33 (g) and (j), and Sec. 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 site safety assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility site atmospheric dispersion characteristics that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in Sec. 50.34(a)(1) of this chapter. Site characteristics must comply with part 100 of this chapter. If the application seeks approval of the site for a specific facility, the application may present the required analyses and request an NRC finding in the ESP that radiological dose criteria of Part 100 are met for the proposed site – design combination. In addition, the application should describe the following: bounding design information may be provided in the case of an application that does not seek approval of the site for a specific facility.

(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 characteristics of the 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 or an evaluation of alternative energy sources, 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 the Federal Emergency Management Agency (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 FEMA, in accord with the applicable provisions of 10 CFR 50.47.

(3) (5) 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 application, 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.

#### Sec. 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 addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR Part 51, 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 characteristics of the 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 or an evaluation of alternative energy sources, 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 FEMA, whether the information required of the applicant by Sec. 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 Sec. 52.17(b)(2)(i) are acceptable, and whether any emergency plans submitted by the applicant under Sec. 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

#### Sec. 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.

#### Sec. 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 Sec. 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 or an evaluation of alternative energy sources. 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 characteristics~~ of 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, ~~except that the provisions of 10 CFR 2.764 shall not apply to ESP proceedings.~~

#### Sec. 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.

#### Sec. 52.24 Issuance of early site permit.

After conducting a hearing under Sec. 52.21 of this subpart and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under Sec. 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 characteristics~~ and the terms and conditions of the early site permit.

#### Sec. 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.

#### Sec. 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.

#### Sec. 52.28 Transfer of early site permit.

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

- (a) ~~An early site permit, or any right thereunder, shall not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer or control of the permit to any person, unless the Commission shall give its consent in writing.~~
- (b) ~~An application for transfer of an early site permit shall include information demonstrating that the applicant satisfies the filing requirements of Section 52.15(a).~~
- (c) ~~The Commission may require any person who submits an application for transfer of an early site permit pursuant to the provisions of this section to file a written consent from the existing holder of the early site permit or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the early site permit.~~
- (d) ~~After appropriate notice to interested persons, including the existing holder of the early site permit, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of an early site permit, if the Commission determines:~~
- ~~(1) That the proposed transferee satisfies the requirements of this section, and~~
  - ~~(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.~~

#### **Sec. 52.29 Application for renewal.**

(a) Not less than twelve nor more than thirty-six months prior to the expiration date, 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 Sec. 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 Sec. 52.31.

#### **Sec. 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.

#### **Sec. 52.33 Duration of renewal.**

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

#### **Sec. 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 Sec. 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.

Sec. 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.

Sec. 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 Sec. 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 Sec. 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 characteristics~~ 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 characteristics~~ 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 an ~~construction permit~~, operating license, duplicate design license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update and identify changes to correct the information that was provided under Sec. 52.17(b), including a summary of the evaluation of each. Changes determined to decrease the effectiveness of emergency plans approved in the ESP, and new emergency planning information provided in the license application, are subject to NRC review and approval 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 Sec. 52.17(b) must be subject to litigation during the ~~construction permit~~, operating license, duplicate design license, or combined license proceeding in the same manner as other issues material to those proceedings.

(c) An applicant for a construction permit, operating license, duplicate design license, or 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, duplicate design license, or combined license proceeding in the same manner as other issues material to those proceedings.

## Subpart B--Early Site Reviews

### Sec. 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 ~~early site permits~~, 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 ~~early site permit applications and~~ applications for the construction and operation

of certain utilization facilities. The utilization facilities are those which are subject to Sec. 51.20(b) of this chapter and are of the type specified in Sec. 50.21(b)(2) or (3) or Sec. 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.

#### **Sec. 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 Sec. Sec. 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 Sec. Sec. 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 Sec. Sec. 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.

#### **Sec. 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.

#### **Sec. 52.46 Referral to the ACRS.**

The portion of the submittal containing information requested of applicants for construction permits by Sec. 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 Sec. 50.34(a)(1) is requested.

#### Sec. 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 Sec. 51.20(b) of this chapter and is of the type specific in Sec. 50.21(b)(2) or (3) or Sec. 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 Sec. 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.

#### Sec. 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 ~~early site permit~~ 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

#### Sec. 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.

#### Sec. 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.

#### Sec. 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.

#### Sec. 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 inspections, tests, analyses, and acceptance criteria (ITAAC) that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a plant that 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 inspections, tests, 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.

- (c) Form of the safety analysis in the application
- (1) In substitution for the final safety analysis report required by 10 CFR 50.34(b), the application for a standard design certification shall contain a generic design control document containing Tier 1 and Tier 2 information.
  - (2) Tier 1 is the portion of the design-related information contained in the generic DCD that is approved and certified. The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:
    - (i) Definitions and general provisions;
    - (ii) Design descriptions;
    - (iii) Inspections, tests, analyses, and acceptance criteria (ITAAC);
    - (iv) Significant site parameters, and
    - (v) Significant interface requirements.
  - (3) Tier 2 is the portion of the design-related information contained in the generic DCD that is approved but not certified. Tier 2 information includes:
    - (i) Remaining information required by 10 CFR 52.47, with the exception of generic technical specifications, conceptual design information, and the probabilistic risk assessment;
    - (ii) Information required for a final safety analysis report under 10 CFR 50.34; and
    - (iii) Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met.

#### Sec. 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.

#### Sec. 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.

#### Sec. 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.

#### Sec. 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.

#### Sec. 52.117 Issuance of standard design certification.

After conducting a rulemaking proceeding under Sec. 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 Sec. 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.

#### Sec. 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 Sec. 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.

#### **Sec. 52.120 – REFERENCING A STANDARD DESIGN CERTIFICATION**

- (a) A standard design certification may be referenced by an applicant for a combined license or by an applicant for a construction permit or operating license under 10 CFR part 50.
- (b) The inspections, tests, analyses and acceptance criteria in a standard design certification are not applicable to an applicant for a part 50 construction permit who references the certification. Prior to issuing an operating license, the Commission shall provide an opportunity for hearing on whether, and shall find that, construction of the plant has been completed in conformity with Tier 1, exclusive of ITAAC, and Tier 2 of the plant-specific design control document, as amended.

#### **Sec. 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 Sec. 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 Sec. 52.123.

#### **Sec. 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.

#### Sec. 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.

#### Sec. 52.127 Finality of standard design certifications.

(a)(1) Notwithstanding any provision in 10 CFR 50.109 ~~and except as provided in paragraph (d) of this section~~ while a standard design certification rule is in effect under Sec. 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:

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

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

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

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

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

(4) While a design certification rule is in effect under Sec. 52.119 or Sec. 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.

(5) 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 Sec. 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 Sec. 50.12(a), the Commission shall consider whether the special circumstances that Sec. 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 Sec. 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. An applicant or licensee may make changes within the scope of the referenced design certification in accordance with the applicable change process for that rule. The applicant and 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.

(d) The applicant for the standard design certification issued under this subpart may file a request for an amendment to the design certification by way of notice and comment rulemaking. The Commission shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act and the Commission's regulation in effect at the time of the amendment. If the amendment request entails such an extensive change to the design certification that essentially new standard design is being proposed, an application for a design certification shall be filed accordance with 52.105 and 52.107 of this part. The amendment will apply to construction permits and combined licenses that reference the standard design certification and that are issued after the effective date of the amendment.

## Subpart E--Standard Design Approvals

**Sec. 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 Sec. 50.22 of this chapter or major portions thereof.

**Sec. 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 Sec. Sec. 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.

**Sec. 52.135 Contents of applications.**

The submittal for review of the standard design must include the information described in Sec. Sec. 50.33 (a) through (d) of this chapter and the applicable technical information required by Sec. 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 Sec. 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 Sec. 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 Sec. 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.

**Sec. 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.

**Sec. 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 15 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.

**Sec. 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.

**Sec. 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**

**Sec. 52.201 Scope of subpart.**

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

**Sec. 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.

#### Sec. 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.

#### Sec. 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.

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

The application must describe the training program required by Sec. 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 ~~fuel load~~ ~~the scheduled date for initial loading of fuel, as provided for in Sec. 52.231(a).~~

#### Sec. 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 characteristics specified in the early site permit and that the requirements of Part 100 are met, unless this information was approved in connection with 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 or that there is reasonable assurance that all terms and conditions will be satisfied during the term of the combined license.

(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 Sec. 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 Sec. 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 Sec. 52.107(a)(2) for level of design information, and must contain the technical information required by Sec. Sec. 52.107(a)(1) (i), (ii), (iv), and (3); Sec. 52.107(b)(2); and, if the design is modular, Sec. 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 Sec. 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 satisfy the additional requirements in Section IV.A of that rule. The final safety analysis report must include a site specific portion that the information approved for incorporation by reference in a design certification rule; describes 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; and demonstrates compliance with the interface requirements established for the design under Sec. 52.107(a)(1); and have available for audit procurement specifications and construction and installation specifications in accordance with Sec. Sec. 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 that affect the design-specific PRA.

(c) The applicant must have available for audit procurement specifications and construction and installation specifications in accordance with Sec. Sec. 52.107(a)(2) and 52.203(b).

(d) 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 that are necessary and sufficient to provide reasonable assurance that, if the inspections,

tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the 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) ~~If the application references a certified standard design, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The NRC staff shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, conclude the prescribed acceptance criteria have been met. The Federal Register notification required by Sec. 52.217, or supplement thereto, must indicate that the application includes this notification and that the NRC staff has concluded that the prescribed acceptance criteria have been met.~~

(e) 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 ~~identifies changes to corrects the information previously provided under Sec. 52.17(b). Changes that decrease the effectiveness of emergency plans approved in the ESP, and new emergency planning information provided in the license application, are subject to NRC review and approval and, and discuss whether the new information materially changes the bases for compliance with the applicable requirements. New information that materially changes the bases for the Commission's determination on the matters in Sec. 52.17(b) must be subject to litigation during the 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.

**Sec. 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.

~~Sec. 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 Sec. 52.231, the licensee shall comply with all requirements in this chapter of Title 10 applicable to holders of construction permits for nuclear power reactors.~~

~~—— (c) After the Commission has authorized operation under Sec. 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 Sec. Sec. 50.55(a), (b) and (d), and 50.58(a).~~

**Sec. 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 (Sec. 2.101) and issuance of a notice of hearing (Sec. 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.

**Sec. 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 Sec. 52.213, in accordance with the finality provisions of this part.

**Sec. 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 characteristics~~ 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).

**Sec. 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 Sec. 52.17(c) the applicant is authorized by Sec. 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 Sec. 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 Sec. 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.

**Sec. 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) and, if the exemption includes any part of the design certification rule, the additional requirements of Sec. 52.127(b)(1) are met.~~

(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.

**Sec. 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 Sec. 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., Sec. 50.54, Sec. 50.59, or Sec. 50.90) or the license.

(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 or the license 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 40 years from the date on which the Commission makes the finding required under Sec. 52.231(g).

Sec. 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 Sec. 52.227(b), as applicable.

(e) The NRC staff shall ensure that the required inspections, tests, and analyses in the ITAAC are performed ~~and prior to operation of the facility, shall conclude that the prescribed acceptance criteria are met. The NRC staff shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, conclude the prescribed acceptance criteria have been met.~~ At appropriate intervals during construction, the NRC shall publish notices in the *Federal Register* of the successful completion of inspections, tests, and analyses.

#### Sec. 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 Sec. 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 Sec. 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 that are the subject of a hearing under paragraph (a) of this section, ITAAC their expiration will expire 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 Sec. 52.227(c) or (d), as applicable.

## Subpart H--Manufacturing Licenses

### Sec. 52.241 Scope of subpart.

(a) Section 101 of the Atomic Energy Act of 1954, as amended, and Sec. 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 of construction," as defined in Sec. 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 Sec. 50.22 of this chapter.

#### Sec. 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 Sec. Sec. 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 Sec. 52.249 has been docketed.

(f) Prohibition against transport of nuclear power reactor manufactured under this subpart. The prohibition in Sec. 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 Sec. 52.249.

#### Sec. 52.245 Filing and contents of applications.

(a) An application for a manufacturing license under this subpart must be submitted, as specified in Sec. 50.4 of this chapter and meet all the requirements of Sec. Sec. 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 Sec. 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.

#### Sec. 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 Sec. 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.

~~Sec. 52.249 Applicability of NRC requirements.~~

~~An applicant shall comply with all requirements in this chapter of Title 10 applicable to applicants for construction permits and operating licenses under this chapter of Title 10, except §§ 50.10(b) and (c), 50.12(b), 50.23, 50.30(d), 50.34(a)(10), 50.34a(e), 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.~~

**Sec. 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.

**Sec. 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 have 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 Sec. 52.245(b), 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.

#### Sec. 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~~ fifteen years from the date of issuance of the manufacturing license.

#### Sec. 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

#### Sec. 52.261 Scope of subpart.

(a) Section 101 of the Atomic Energy Act of 1954, as amended, and Sec. 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 Sec. 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.**

**Sec. 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 Sec. 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.

**Sec. 52.265 Filing and contents of applications.**

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

(b) For the technical information required by Sec. Sec. 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.

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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.

(c) Applications for operating licenses submitted pursuant to this subpart must include the information required by Sec. Sec. 50.33, 50.34(b) and (c), and 50.34a(c) of this chapter. The applicant shall also submit the information required by Sec. 51.53 of this chapter. For the technical information required by Sec. Sec. 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

Sec. 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.

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

(b) The regulations in this part ~~52~~ that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: Sec. Sec. 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, ~~52.35~~, 52.37, 52.39, 52.101, 52.103, 52.105, 52.107, 52.109, 52.111, 52.113, 52.115, 52.117, 52.119, ~~52.120~~, 52.121, 52.123, 52.125, ~~52.127~~, 52.201, 52.203, 52.205, 52.207, 52.209, 52.211, 52.213, 52.215, 52.217, 52.219, 52.221, ~~52.223~~, 52.225, 52.227, ~~52.229~~, 52.231, 52.401, 52.403 and Appendices A, B, and C.

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

~~Except as noted, same changes recommended for Appendix B (System 80+) and Appendix C (AP600)~~

### 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, the design-specific PRA 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. Change or departure means a modification or addition to, or removal from, the facility or procedures that affects: (1) a design function, (2) method of performing or controlling the function, or (3) an evaluation that demonstrates that intended functions will be accomplished.

H. 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.

I. 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 characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

#### IV. Additional Requirements and Restrictions

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

1. Incorporate by reference, as part of its application, this appendix;

2. Physically include, as part of its application:

a. A plant-specific DCD containing the generic DCD same information for the U.S. ABWR design 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 the generic DCD 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.
4. Appendix A to 10 CFR part 100 - - Operating Basis Earthquake [this comment applies to ABWR only]

## 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 Sec. 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 a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

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

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

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

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.231(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 the change satisfies the requirements of 50.109, and 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. A departure from an operational requirement that was completely reviewed and approved in the design certification rulemaking does not require an exemption unless the departure requires Commission approval under VIII.B.5 of this appendix. 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 information concerning operational requirements that was not completely reviewed and approved in the design certification rulemaking 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, ~~conclude~~ 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 that, which are the subject of a Sec. 52.231(a) hearing, ITAAC their expiration will expire 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 generic 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 ~~on departures from the generic 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

28. 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).

29. Section 72.210 is revised to read as follows:

**Sec. 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.

30. In Sec. 72.218, paragraph (b) is revised to read as follows:

**Sec. 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**

31. 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).

32. In Sec. 73.1, paragraph (b)(1)(i) is revised to read as follows:

Sec. 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.

\* \* \* \* \*

#### PART 140--FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY REQUIREMENTS

33. 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).

34. In Sec. 140.2, paragraph (a)(1) is revised to read as follows:

Sec. 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 to operate a nuclear reactor, and

\* \* \* \* \*

35. Section 140.10 is revised to read as follows:

Sec. 140.10 Scope.

This subpart applies to applicants for and holders of licenses issued pursuant to 10 CFR parts 50, 52, or 54 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.

36. Section 140.11 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

Sec. 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 Sec. 52.231(g).

37. Section 140.13 is revised to read as follows:

**Sec. 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 Sec. 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 Sec. 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 Sec. 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**

38. 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). 39. In Sec. 170.2, paragraphs (g) and (k) are revised to read as follows:

Sec. 170.2 Scope.

\* \* \* \* \*

(g) An applicant for or holder of a production or utilization facility construction permit or operating license issued under 10 CFR part 50, or an approval, certification, permit, or license issued under 10 CFR part 52;

\*\*\*\*\*

(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;

\*\*\*\*\*

§ 8.5 The reference in 10 CCR 170.3 to 10 CFR part 52, Appendix M, should be replaced with a reference to 10 CFR part 52, subpart H.

**PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC**

39. Section 171.15(a) is revised to read as follows:

(a) Each person licensed to operate a power, test, or research reactor under part 50 or under part 52 after the Commission makes the finding specified in 10 CFR 52.231; each person holding a part 50 or part 52 power reactor license that is in decommissioning or possession only status, except those that have no spent fuel on-site; and each person holding a part 72 license who does not hold a part 50 or part 52 license shall pay the annual fee for each license held at any time during the Federal FY in which the fee is due. This paragraph does not apply to test and research reactors exempted under § 171.11(a).